REPORT NO. 285
SEPTEMBER 30, 1964

COMMUNICABLE DISEASE CENTER

POLIOMYELITIS

SURVEILLANCE

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U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

PREFACE

Summarized in this report is information received from State Health Departments, university investigators, virology laboratories and other pertinent sources, domestic and foreign. Much of the information is preliminary. It is intended primarily for the use of those with responsibility for disease control activities. Anyone desiring to quote this report should contact the original investigator for confirmation and interpretation.

Contributions to the Surveillance Report are most welcome. Please address to:
Chief, Poliomyelitis Surveillance Unit, Communicable Disease Center, Atlanta, Georgia 30333

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SUMMARY

Eighty-six cases of poliomyelitis, 69 paralytic, have been reported through the week ended September 19, 1964; less than one-third the number of total and paralytic cases reported during the corresponding period in 1963; the previous record low year.

A brief description of the 56 paralytic cases, for which individual poliomyelitis surveillance case records have been received, is included in Section II.

The supplement to this PSU Report includes the report of the Surgeon General's Advisory Committee on Oral polio vaccine. This committee has reviewed the 87 cases of paralytic disease associated with oral polio vaccine occurring in non-epidemic areas since licensure. A minority report issued by Dr. Albert B. Sabin is also included in the supplement along with an epidemiologic summary of the problem and a listing of the associated cases studied.

I. CURRENT POLIOMYELITIS MORBIDITY TRENDS

Eighty-six cases of poliomyelitis, 69 paralytic, have been reported through the week ending September 19, 1964 (See Table 1). These totals represent less than one-third the number of total and paralytic cases reported during the corresponding period in 1963 as shown below:

Poliomyelitis (Cumulated Weekly) Through 38th Week for Five Years

	1964	1963	1962	1961	1960
Paralytic	69	235	439	557	1446
Total	86	276	565	849	2111

The low incidence of poliomyelitis during 1964 is even more impressive when the current reporting during the past six weeks is compared to previous years (See Figure 1 on page 8):

Six-Week Totals (33rd thru 38th Week) for Five Years

	1964	1963	1962	1961	1960
Paralytic	13	103	164	283	669
Total	19	117	201	436	1037

There have been no outbreaks reported thus far in 1964. The only states that have reported more than 5 paralytic cases are New York (9) and Florida (8).

II. ROUTINE POLIOMYELITIS SURVEILLANCE - 1964

The Polio Surveillance Unit has received individual surveillance case records for 56 of the 69 paralytic cases reported through September 19, 1964. The 56 cases are shown below by age and sex. Seventy-seven percent of the cases have been males.

Age Group	Males	Females	Total
0-4	16	6	22
5-9	6	2	8
10-14	2	2	4
15-19	5	0	5
20-29	2	1	3
30-39	4	1	5
40+	8	1	9
Total	43	13	56

Twenty of the 56 cases have occurred within 30 days following ingestion of oral poliomyelitis vaccine (See Special Report in Supplement to this PSU Report). A line listing of these 20 cases is shown on pages 4 and 5. Fifteen of the 20 vaccine associated cases are 15 years of age or older. Nine of the 20 cases followed Type III oral polio vaccine, 6 followed trivalent, 3 followed Type I and 2 followed Type II vaccine.

1964 Paralytic Poliomyelitis Cases Occurring Within 30 Days After OPV

State	County	Age	Sex	Onset	Doses IPV	Interval (Days) OPV to Onset I	II	III	Tri.	Virus Isol.	60-Day Status***
Ala.	Escambia	18	M	1-26	0	-	-	21	-	III	3
Ala.	Escambia	28	M	3-28	0	-	-	20	-	III	
Colo.	Pueblo	5 mos.	F	2-4	0	-	23	-	-	II	1
Fla.	**	25	M	1-31	Unk.	-	-	12	-	III	1
*Fla.	Dade	4 mos.	F	4-29	0	-	-	-	13	I	4
Ga.	Bartow	15	M	3-5	5	25	-	-	-	Neg.	3
Ill.	Adams	3 mos.	M	1-28	Unk.	-	-	11	-	III	
Md.	Pr. Georges	15	M	5-9	0	20	-	-	-	I	4
*Mo.	Dunklin	37	F	3-24	0	29	-	2	-	Neg.	
Nebr.	Lancaster	41	M	3-14	Unk.	2yrs.	2yrs.	5	-	-	3
N.J.	Mercer	35	M	2-1	0	48	-	13	-	Neg.	3
N.J.	Morris	41	F	3-23	4	63	-	22	-	Neg.	2
N.Y.	Nassau	37	M	4-27	0	-	-	-	8	II	2
N.Y.	Fulton	5	M	6-29	3	-	-	-	11	I, II, III	1
N.C.	Alamance	43	M	3-16	0	-	-	-	15	I	5
N.C.	Forsyth	43	M	3-9	0	-	-	-	8	II	4

State	County	Age	Sex	Onset	Doses IPV	Interval (Days) OPV to Onset I	II	III	Tri.	Virus Isol.	60-Day Status***
N.C.	Mecklenburg	48	M	4-7	0	-	-	-	16	III	3
N.C.	Lenoir	49	M	6-14	0	84	28	56	-	-	4
Ohio	Lucas	8 mos.	M	4-6	0	38	-	13	-	III	3
*Wis.	Dane	33	M	3-12	Unk.	60	-	18	-	-	2

* Cases reported after Surgeon General's Committee meeting of July 17-18, 1964.

** Reported by Florida State Department of Health as a Florida case. Case received vaccine in Duval County, Florida but resides in Kingsland, Georgia.

*** Clinical Status at 60 Days:

1 - Complete Recovery
2 - Minor Involvement
3 - Significant disability
4 - Severely disabled
5 - Death

Table 1

TREND OF 1964 POLIOMYELITIS INCIDENCE

State and Region	Cumulative 1964	Cases Reported to CDC For Week Ending 8/15	8/22	8/29	9/5	9/12	9/19	Six-Week Total	Comparable Six-Week Totals in 1963	1962	1961
UNITED STATES											
Paralytic	69	1	3	2	1	2	4	13	103	164	283
Nonparalytic	10	-	1	-	1	-	-	2	10	28	109
Unspecified	7	-	-	-	1	2	1	4	4	9	44
Total	86	1	4	2	3	4	5	19	117	201	436
NEW ENGLAND											
Paralytic	2	-	-	-	-	1	-	1	2	-	12
Total	2	-	-	-	-	1	-	1	2	-	16
Maine	-	-	-	-	-	-	-	-	-	-	2
New Hampshire	-	-	-	-	-	-	-	-	-	-	1
Vermont	-	-	-	-	-	-	-	-	1	-	3
Massachusetts	-	-	-	-	-	-	-	-	1	-	8
Rhode Island	-	-	-	-	-	-	-	-	-	-	-
Connecticut	2	-	-	-	-	1	-	1	-	-	2
MIDDLE ATLANTIC											
Paralytic	11	-	1	-	-	-	-	1	44	16	110
Total	12	-	2	-	-	-	-	2	53	20	173
New York	10	-	2	-	-	-	-	2	-	9	138
New Jersey	2	-	-	-	-	-	-	-	-	3	16
Pennsylvania	-	-	-	-	-	-	-	-	53	8	19
EAST NORTH CENTRAL											
Paralytic	13	-	1	1	1	-	1	4	11	21	34
Total	18	-	1	1	2	2	2	8	13	28	55
Ohio	2	-	-	-	-	-	-	-	1	8	11
Indiana	6	-	1	-	-	2	2	5	-	4	6
Illinois	5	-	-	-	-	-	-	-	3	12	9
Michigan	3	-	-	1	1	-	-	2	6	2	15
Wisconsin	2	-	-	-	1	-	-	1	3	2	14
WEST NORTH CENTRAL											
Paralytic	6	-	-	1	-	1	1	3	-	9	13
Total	7	-	-	1	-	1	1	3	-	12	27
Minnesota	2	-	-	-	-	1	-	1	-	3	3
Iowa	-	-	-	-	-	-	-	-	-	-	13
Missouri	3	-	-	1	-	-	-	1	-	2	4
North Dakota	1	-	-	-	-	-	1	1	-	1	1
South Dakota	-	-	-	-	-	-	-	-	-	1	1
Nebraska	-	-	-	-	-	-	-	-	-	5	3
Kansas	1	-	-	-	-	-	-	-	-	-	2

Table 1 (Continued)

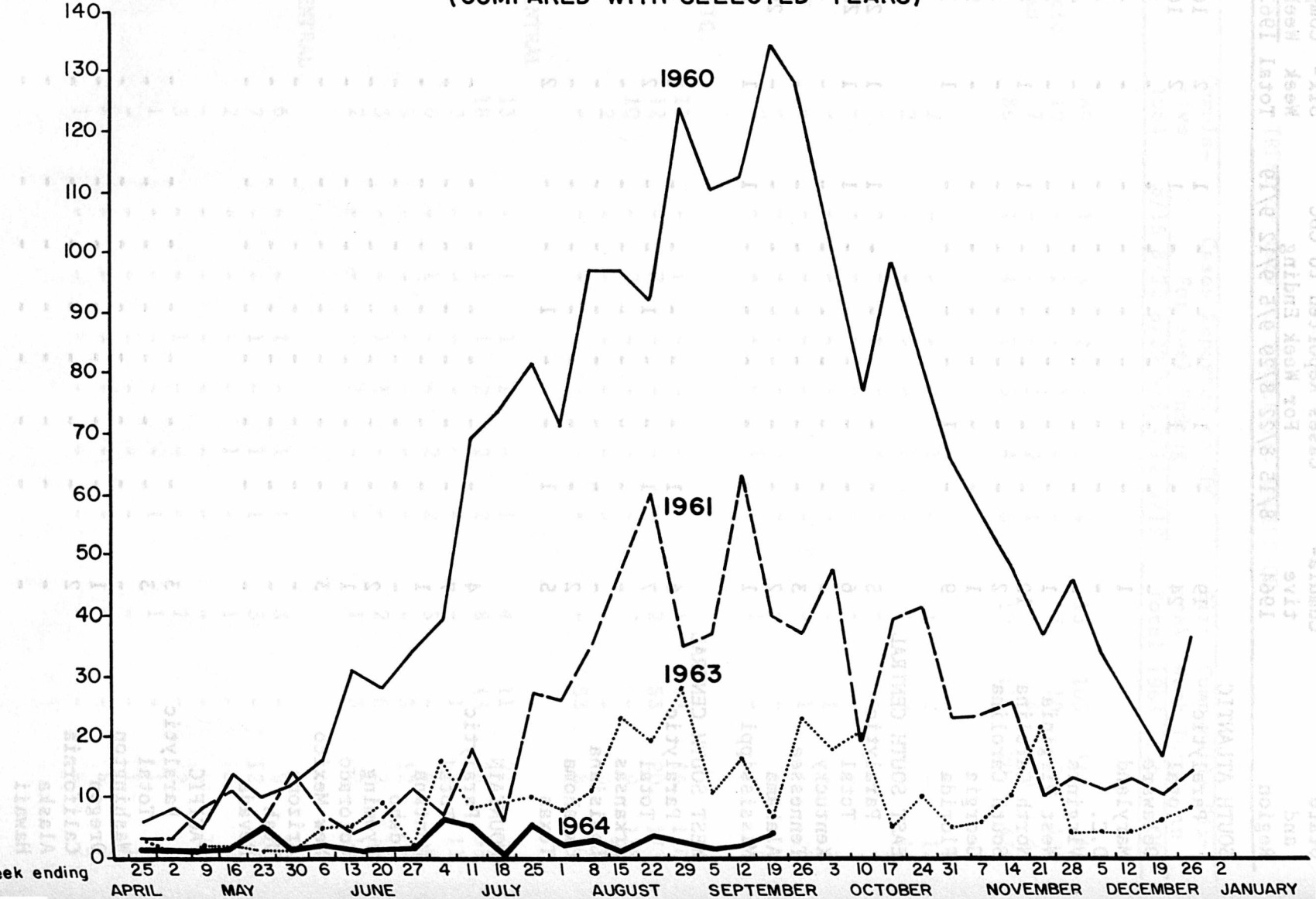
State and Region	Cumulative 1964	Cases Reported to CDC For Week Ending 8/15	8/22	8/29	9/5	9/12	9/19	Six-Week Total	Comparable Six-Week Totals in 1963	1962	1961
SOUTH ATLANTIC											
Paralytic	19	-	1	-	-	-	1	2	16	18	42
Total	24	-	1	-	-	-	1	2	16	19	59
Delaware	-	-	-	-	-	-	-	-	1	-	-
Maryland	1	-	-	-	-	-	-	-	-	-	11
D.C.	-	-	-	-	-	-	-	-	-	1	-
Virginia	-	-	-	-	-	-	-	-	4	2	6
West Virginia	1	-	-	-	-	-	-	-	-	2	10
North Carolina	10	-	-	-	-	-	1	1	-	3	7
South Carolina	2	-	-	-	-	-	-	-	1	4	7
Georgia	1	-	-	-	-	-	-	-	9	6	5
Florida	9	-	1	-	-	-	-	1	1	1	13
EAST SOUTH CENTRAL											
Paralytic	5	-	-	-	-	-	1	1	26	26	21
Total	6	-	-	-	-	-	1	1	28	32	30
Kentucky	-	-	-	-	-	-	-	-	-	12	3
Tennessee	3	-	-	-	-	-	-	-	5	5	10
Alabama	2	-	-	-	-	-	-	-	20	14	4
Mississippi	1	-	-	-	-	-	1	1	3	1	13
WEST SOUTH CENTRAL											
Paralytic	6	1	-	-	-	-	-	1	2	53	23
Total	7	1	-	-	1	-	-	2	3	67	42
Arkansas	-	-	-	-	-	-	-	-	1	4	13
Louisiana	-	-	-	-	-	-	-	-	-	8	13
Oklahoma	2	-	-	-	-	-	-	-	-	8	1
Texas	5	1	-	-	1	-	-	2	2	47	15
MOUNTAIN											
Paralytic	4	-	-	-	-	-	-	-	-	-	3
Total	7	-	-	-	-	-	-	-	-	2	6
Montana	1	-	-	-	-	-	-	-	-	-	-
Idaho	-	-	-	-	-	-	-	-	-	1	3
Wyoming	2	-	-	-	-	-	-	-	-	1	-
Colorado	1	-	-	-	-	-	-	-	-	-	2
New Mexico	3	-	-	-	-	-	-	-	-	-	-
Arizona	-	-	-	-	-	-	-	-	-	-	-
Utah	-	-	-	-	-	-	-	-	-	-	1
Nevada	-	-	-	-	-	-	-	-	-	-	-
PACIFIC											
Paralytic	3	-	-	-	-	-	-	-	2	21	25
Total	3	-	-	-	-	-	-	-	2	21	28
Washington	-	-	-	-	-	-	-	-	1	2	7
Oregon	1	-	-	-	-	-	-	-	-	-	3
California	2	-	-	-	-	-	-	-	1	19	17
Alaska	-	-	-	-	-	-	-	-	-	-	-
Hawaii	-	-	-	-	-	-	-	-	-	-	1
Puerto Rico	-	-	-	-	-	-	-	-	1	2	1

FIGURE I

CURRENT INCIDENCE OF PARALYTIC POLIOMYELITIS

BY WEEK OF REPORT - UNITED STATES

(COMPARED WITH SELECTED YEARS)



Key to all disease surveillance activities are those in each State who serve the function as State epidemiologists. Responsible for the collection, intrepretation and transmission of data and epidemiological information from their individual States, the State epidemiologists perform a most vital role. Their major contributions to the evolution of this report are gratefully acknowledged.

STATE	NAME
Alabama	Dr. W. H. Y. Smith
Alaska	
Arizona	Dr. Philip M. Hotchkiss
Arkansas	Dr. Wm. L. Bunch, Jr.
California	Dr. Philip K. Condit
Colorado	Dr. C. S. Mollohan
Connecticut	Dr. James C. Hart
Delaware	Dr. Floyd I. Hudson
D. C.	Dr. William E. Long
Florida	Dr. E. Charlton Prather
Georgia	Dr. W. J. Murphy
Hawaii	Dr. W. F. Lyons
Idaho	Dr. John A. Mather
Illinois	Dr. Norman J. Rose
Indiana	Dr. A. L. Marshall, Jr.
Iowa	Dr. Ralph H. Heeren
Kansas	Dr. Don E. Wilcox
Kentucky	Mr. J. Clifford Todd
Louisiana	Dr. John M. Bruce
Maine	Dr. Dean Fisher
Maine	Mrs. Margaret H. Oakes
Maryland	Dr. John H. Janney
Massachusetts	Dr. Nicholas J. Fiumara
Michigan	Dr. George H. Agate
Minnesota	Dr. D. S. Fleming
Mississippi	Dr. Durward L. Blakey
Missouri	Dr. E. A. Belden
Montana	Dr. Mary E. Soules
Nebraska	Dr. E. A. Rogers
Nevada	Dr. B. A. Winne
New Hampshire	Dr. William Prince
New Jersey	Dr. W. J. Dougherty
New York State	Dr. Robert M. Albrecht
New York City	Dr. Harold T. Fuerst
New Mexico	Dr. H. G. Doran, Jr.
North Carolina	Dr. Jacob Koomen
North Dakota	Mr. Kenneth Mosser
Ohio	Dr. Calvin B. Spencer
Oklahoma	Dr. F. R. Hassler
Oregon	Dr. Grant Skinner
Pennsylvania	Dr. W. D. Schrack, Jr.
Puerto Rico	Dr. Rafael A. Timothee
Rhode Island	Dr. James E. Bowes
South Carolina	Dr. G. E. McDaniel
South Dakota	Dr. G. J. Van Heuvelen
Tennessee	Dr. C. B. Tucker
Texas	Dr. Van C. Tipton
Utah	Dr. Elton Newman
Vermont	Dr. Linus J. Leavens
Virginia	Dr. James B. Kenley
Washington	Dr. E. A. Ager
West Virginia	Dr. L. A. Dickerson
Wisconsin	Dr. Josef Preizler
Wyoming	Dr. Helen A. Moore

FIGURE I

CURRENT INCIDENCE OF PARALYTIC POLIOMYELITIS
BY WEEK OF REPORT - UNITED STATES
(COMPARED WITH SELECTED YEARS)

SUPPLEMENT TO POLIOMYELITIS SURVEILLANCE REPORT
NO. 285

September 30, 1964

ASSOCIATION OF PARALYTIC DISEASE WITH ORAL POLIO VACCINES

I. Press Release

II.* Report of a Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General of the Public Health Service

III.* Comments on the Report of the Special Advisory Committee By Albert B. Sabin

IV.* Paralytic Disease Associated with Oral Polio Vaccines, By D. A. Henderson, J. J. Witte, L. Morris, and A. D. Langmuir

V. Listing of Reported Cases of Paralytic Poliomyelitis Occurring Within 30 Days After Receiving the Oral Poliomyelitis Vaccines, 1961-1964

* Appearing in The Journal of the American Medical Association dated October 5, 1964.

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U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Washington 25, D. C.

FOR IMMEDIATE RELEASE
Wednesday, September 23, 1964

HEW-C60

A special advisory committee to the Surgeon General of the Public Health Service, Department of Health, Education, and Welfare, urged today renewed drives by local communities during the fall and winter to vaccinate the younger age group against poliomyelitis.

The report was prepared by a special advisory committee on oral poliomyelitis vaccine and was made public today by Surgeon General Luther L. Terry.

The committee's report said that the age group to be immunized and the vaccine chosen for use should be determined locally. The committee said, however, that in its view the oral vaccination of persons over 18 should "generally be recommended only in those situations in which unusual exposure to poliomyelitis might be anticipated, such as epidemics, entry into military service, and travel to other countries."

The committee recommended strongly the immunization of infants during their first year of life and the routine immunization of all children on entering school.

Dr. Terry, in releasing the report, said that the Public Health Service was accepting the committee's recommendations. He pointed out that the shift in emphasis away from adults toward the younger age groups was forecast in a committee report of December 1962. The advisory committee at that time emphasized the importance of concentrating on the

immunization of the younger age groups and noted a "very small risk" incident to the use of oral vaccine in persons 30 years of age and over.

The current committee report also recommends alteration in the sequence of administering monovalent vaccines, with Type II the first to be given. The newly-recommended order is Type II, I, and III.

Dr. Albert Sabin, developer of the oral vaccine and a member of the committee, filed a report dissenting from the committee's recommendations and calling for the continued immunization of all age groups.

The Service is making available the full text of both reports to State Health Officers, professional organizations, and other interested agencies, Dr. Terry said.

The committee's recommendations were based on an exhaustive analysis of 87 reported cases of "polio-like illness associated with the administration of oral vaccines" which have occurred in non-epidemic areas since December 1961.

These cases were considered by the committee on the basis of whether or not they were "compatible with the possibility of having been induced by the vaccine."

It concluded that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests available can provide a definitive answer. Nevertheless, the committee said, "Considering the epidemiological evidence developed with respect to the total group of 'compatible' cases, the committee believes that at least some of these cases were caused by the vaccine."

(more)

The extent of the "risk factor", according to the report, is, for Type III, only 1 case in 2.5 million doses administered; for Type I, only 1 in 6 million; and for Type II, only 1 in 50 million.

With respect to the very minimal risk, Dr. Terry emphasized that there should be no apprehension whatsoever among those who have already taken the oral vaccine.

In its analysis of the 87 cases, the committee found 57 which they considered "compatible."

The "compatible" cases, the report said, occurred largely among adults. Most were widely scattered throughout the country. The onset of illness fell between 4 and 28 days following vaccine administration.

"There was no apparent association of cases with specific lots of vaccine or vaccines produced by a particular manufacturer," the report added.

In urging a renewed effort to vaccinate those still susceptible, most of them poorly-immunized children in economically-depressed population groups, the committee cited the spectacular decline of polio during recent years.

The decline has been from an annual rate of 14.6 cases per 100,000 during 1950-54 to a rate of 1.8 for 1957-61. This represents a decrease of 88 percent.

"On the basis of reports to date, less than 150 cases of paralytic poliomyelitis may be anticipated for the entire year (of 1964)," the report added.

In commenting on this phase of the report, Surgeon General Terry said:

"When you compare this year's record low with the 54,000

cases of polio reported in 1952, the triumph against polio is an historic achievement in preventive medicine. This great victory has been made possible by the work of two extraordinarily dedicated scientists--Dr. Jonas Salk and Dr. Albert Sabin--and it has come to pass through the devoted efforts of hundreds of organizations and thousands of individuals," Dr. Terry said.

The Surgeon General added: "I heartily and enthusiastically endorse the committee's primary recommendation that every effort be made for the continuing vaccination of infants and younger age groups. Only through this means can we achieve total victory over polio."

Dr. Terry praised the committee for a "painstaking, conscientious and thorough report in the public interest."

Members of the Committee were:

Dr. Ernest A. Ager, State Department of Health, Olympia, Washington

Dr. David Bodian, The Johns Hopkins University, Baltimore, Maryland

Dr. Gordon C. Brown, University of Michigan School of Public Health, Ann Arbor

Dr. Alice D. Chenoweth, Childrens Bureau, Washington, D.C.

Dr. Geoffrey Edsall, Massachusetts Department of Public Health, Boston

Dr. John P. Fox, Public Health Research Institute of New York, New York

Dr. James L. Goddard, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. A. L. Gray, Mississippi State Board of Health, Jackson

Dr. William McD. Hammon, University of Pittsburgh, Pa.

Dr. Donald A. Henderson, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. David T. Karzon, Childrens Hospital, University of Buffalo, New York, (unable to attend)

(more)

Dr. Alexander D. Langmuir, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. Theodore A. Montgomery, California State Department of Public Health, Berkeley

Dr. Roderick Murray, National Institutes of Health, Public Health Service, Bethesda, Maryland

Dr. Albert Sabin, The Childrens Hospital Research Foundation, Cincinnati, Ohio

Dr. Edward B. Shaw, University of California School of Medicine, San Francisco

Dr. Paul F. Wehrle, University of Southern California School of Medicine, Los Angeles

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Report of a Special Advisory Committee
on Oral Poliomyelitis Vaccine to the
Surgeon General of the Public Health Service
July 17-18, 1964

A special advisory committee on oral poliomyelitis vaccines met at the Communicable Disease Center in Atlanta on July 17-18. The group consisted of the recently formed Public Health Service Advisory Committee on Immunization Practices and members of the Special Oral Poliomyelitis Vaccine Advisory Committee that met during 1962. The Surgeon General served as Chairman of the group; a list of the members is attached.

The Committee reviewed data regarding the surveillance of poliomyelitis in this country from 1955-1961 when inactivated poliomyelitis vaccines were used and from 1961 to date when oral poliomyelitis vaccines have come into use with increasing frequency. Particular attention was directed to reported cases of paralytic disease occurring in association with the administration of oral vaccines. Recommendations were developed for the continuing use of monovalent and trivalent oral poliomyelitis vaccines.

Surveillance

The incidence of paralytic poliomyelitis declined from an annual level of 14.6 cases per 100,000 in the 5-year period 1950-1954 to a rate of approximately 1.8 for the period 1957-1961. This constituted a decrease of 88 percent which can be attributed in large measure to the use of inactivated poliomyelitis vaccine. Since 1961 the incidence has further declined; the paralytic case rate for 1963 was 0.2. A further decrease

in cases has been observed during the first 6 months of 1964. On the basis of reports to date, less than 150 cases of paralytic poliomyelitis may be anticipated for the entire year. Epidemics of poliomyelitis have become rare. The comparatively few which occurred in 1963 were numerically small and confined largely to poorly immunized preschool children in economically depressed population groups.

Utilization of Poliomyelitis Vaccines

From 1955 through 1961, 400 million doses of inactivated poliomyelitis vaccine were distributed in the United States. A high proportion of the children and more than half of the adults in the population received one or more injections of the vaccine. Inactivated vaccine has continued to be used in routine pediatric practice and public health immunization clinics. In 1962, 36 million doses were distributed and, in 1963, the amount declined to 19 million doses.

Since 1961 approximately 100 million doses of each of the three types of oral poliomyelitis vaccine have been distributed. These vaccines have been used largely in community-wide immunization programs and for epidemic control purposes. They also have been employed to an increasing extent in routine pediatric immunization practice.

Trivalent oral poliomyelitis vaccine, available since June, 1963, has been used primarily in routine immunization and recently in a few community-wide programs.

Vaccine Associated Cases

During 1962, the Special Advisory Committee met on a number of occasions and reviewed in detail all reported cases of polio-like illness

associated with the administration of oral vaccines. Eighteen cases of paralytic disease were considered by the Committee to be "compatible with the possibility of having been induced by the vaccine." Of these, 11 followed Type III vaccine and 7 came after Type I vaccine. Most of the cases occurred in adults. The "maximum potential risk" was stated to be "of the order of one per million or less over-all, but higher for those over 30 years of age." The Committee at that time recommended that community programs of immunization be continued but that "in adults especially above the age of 30, vaccination should be used --- only with the full recognition of its very small risk."

Since December 1962, a number of additional reports have been received of paralytic poliomyelitis cases which occurred within 30 days after receiving oral poliomyelitis vaccines. At the July 17-18, 1964 meeting, the Committee considered in detail the 87 such cases reported from non-epidemic areas since oral vaccines became available.* The clinical, laboratory and epidemiological data pertaining to each of these cases were carefully reviewed. Those cases meeting the criteria listed below were placed in a category termed "compatible" with vaccine association:

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine in question and with an onset of paralysis not sooner than 6 days after the feeding.
2. Significant residual lower motor neuron paralysis.

* This total of 87 includes both the cases considered in 1962 on which additional information has become available and all newly reported cases.

3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.

4. No evidence of: (a) upper motor neuron disease, (b) definite sensory loss, or (c) progression or recurrence of paralytic illness one month or more after onset.

Of the 87 cases considered, 57 were judged "compatible", 21 were excluded after careful consideration. In the case of 9, the data were insufficient upon which to make a judgment.

Of the 57 cases considered "compatible", 15 followed Type I vaccine, 2 followed Type II, 36 followed Type III and 4 followed trivalent vaccine administration.*

These "compatible" cases occurred largely among adults, 44 being 15 years of age and older, 8 over 50 years. In the group were 46 male and 11 female cases; 35 had received no inactivated vaccine; 14 had received 3 or more doses. The cases were widely scattered throughout the country except for 8 Type III "compatible" cases in different areas in Nebraska, 5 Type I associated cases in Northern California, and 3 trivalent vaccine associated cases, all in adults, in North Carolina. The onsets of illness of the cases fell between 4 and 28 days with the majority occurring within 8 to 21 days following vaccine administration. There was no apparent association of cases with specific lots of vaccine or vaccines produced by a particular manufacturer.

*Employing the point binomial it is possible to make an approximate test of statistical significance of these findings. Assuming independence of risk and recognizing that essentially equal amounts of oral vaccine of each type were distributed the probability that 2 Type II cases and 15 Type I cases could have occurred by chance alone is 2.4 in a thousand (P=0.0024); the probability of 2 Type II cases and 36 Type III cases is one in 185 million (P=0.000000005).

Evaluation of the Risk

The Committee recognizes that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests available can provide a definitive answer. Nevertheless, considering the epidemiological evidence developed with respect to the total group of compatible cases, the Committee believes that at least some of these cases were caused by the vaccine.

The extent of the risk can be estimated from the incidence rates per million doses of the vaccine which have been distributed for use. It was small and differed by type of vaccine and age. For Type III vaccine the over-all rate is 0.40 per million doses; for Type I, 0.16; and for Type II, .02. For trivalent vaccine the data available regarding amounts of vaccine distributed are limited and the rate cannot be estimated.

In the age group under five, 6 cases followed Type III vaccine administration, giving an estimated rate of 0.53 per million doses; 2 cases followed Type I vaccine for a rate of 0.17. In the 5-14 year age group the rates for both vaccines fell below 0.10. In older age groups, the rates are higher, particularly for Type III vaccine. In the age group from 20-39 it exceeds 0.50, or one case per 2,000,000 doses distributed.

From this evidence it was inferred that the risk is highest for Type III; the evidence of risk is less definite for Type I vaccine. For Type II vaccine the rate is so low as to suggest absence of risk.

The Committee recognized that many additional factors enter into the appraisal of the extent of the risk in various population groups.

For example, the risk following Type III vaccine in adults is higher in males than females. Furthermore, unimmunized adults who have lived in rural areas and those from upper socioeconomic groups would appear to be at greater risk than those who have had more opportunity for prior exposure to naturally spreading polioviruses.

Conclusions

In view of these considerations the Committee agreed to the following:

1. The extent of the assessed risk is sufficiently low relative to the risk of naturally occurring illness in children to warrant continuation and intensification of the poliomyelitis immunization program throughout the nation, although with some changes in emphasis.

2. Primary emphasis should be given in all communities to the immunization of all infants during their first year of life. All communities which have not already organized continuing programs for the effective immunization of their infants and preschool children in all socioeconomic groups are urged to do so.

   (The success of such programs is requisite for attaining the goal of the elimination of paralytic poliomyelitis since it is primarily those younger children who serve to transmit the natural infection within the community.)

3. Communities which have not yet embarked upon mass immunization programs are encouraged to do so during the coming fall and winter (1964-65).

(Such programs will be of value only if they succeed in reaching unimmunized persons, particularly preschool children, in lower socioeconomic areas. Before embarking on mass programs, all communities should develop definitive plans for continuing immunization programs to care for the new susceptibles born into or moving into the community.)

4. The age groups to be immunized in mass programs and the vaccine chosen for use should be determined locally. The vaccination of individuals over school age (about 18 years) should generally be recommended only in those situations in which unusual exposure to poliomyelitis might be anticipated, such as epidemics, entry into military service, and travel to other countries.

5. Vaccination of children on entry to school should become a routine practice.

(It is recognized that the duration of immunity following oral vaccine has not yet been adequately measured, but it is also recognized that the occasion of entry to school provides an excellent opportunity to reinforce artificial immunity from earlier vaccination and to provide primary immunization for those who may have been missed.)

6. The order of administration of the monovalent vaccines, previously given in the order of Types I, III, and II now should be altered so that Type II would be first administered.

(From serological studies and epidemiological evidence, Type II infection appears to confer some heterologous immunity against Types I and III infection. Giving Type II vaccine first should theoretically further diminish the slight risks associated with the other vaccine types. Furthermore at the present time with poliomyelitis incidence rates at an all-time low and with epidemics rare, there is no longer an overriding need to give Type I vaccine first as was believed to be important in the past.)

Recommended Immunization Practices Using Oral Polio Vaccines

A. Primary Immunization

1. For Infants

Either monovalent or trivalent vaccines may be used for primary immunization. If monovalent vaccines are used the schedule should be:

Type II, at the time of the first DPT injection.

Type I, at the time of the second DPT injection.

Type III, at the time of the third DPT injection.

If trivalent vaccine is used it should be given at the time of the first and third DPT immunizations. In both instances a dose of trivalent vaccine at the end of the first year of life is recommended to complete the primary

immunization series. The final dose in breast fed infants should be delayed until cessation of breast feeding.

(The Committee recognized that many pediatricians may give DPT injections at monthly intervals and that therefore the present recommendation may lead to the administration of Type I vaccine at less than the optimal interval (2 months) after Type II vaccine. The many administrative advantages of full coordination of oral polio vaccine with DPT immunization were felt to override this slight disadvantage. The Committee stresses the importance of the final dose of trivalent vaccine at one year of age as an essential part of the primary immunization schedule.

2. For All Others

If monovalent vaccines are used:

Type II.

Type I, not less than 8 weeks after Type II.

Type III, not less than 6 weeks after Type I.

If trivalent vaccine is used:

Two doses should be given with an 8-week interval between doses.

B. Recommendations Concerning Further Immunization Using Oral Polio Vaccines

Further immunization should be given:

1. At the time of entry into elementary school.

(A single dose of trivalent vaccine is indicated except for those who have had no previous vaccination in whom a primary series should be given.)

2. To those at unusual risk such as persons resident in epidemic areas, individuals who are traveling abroad and those entering the military services.

(Further recommendations regarding the desirability of additional immunizations must await the results of longer term studies and continuing surveillance.)

C. Recommendations Concerning Community Immunization Programs Using Oral Polio Vaccines

1. Monovalent vaccines are preferred and should be administered in accordance with the following schedule:

Type II.

Type I, not less than 8 weeks after Type II.

Type III, not less than 6 weeks after Type I.

2. When circumstances exist which make the use of trivalent vaccine more desirable for the conduct of mass immunization programs, it is recommended that at least 8 weeks elapse between the first and second feedings.

D. Recommendations Concerning Specific Problems

1. The Committee knows of no data which would contraindicate use of oral polio vaccine during pregnancy *per se*.

2. With naturally occurring poliomyelitis at its present low level, the Committee sees no need to delay indicated tonsillectomies because of the season of the year,

provided that the child has been adequately immunized. Recent oral vaccine administration also should not serve as a contraindication to needed tonsillectomy.

Special Advisory Committee on Oral Poliomyelitis Vaccine
to the Surgeon General of the Public Health Service
1964

Dr. Luther L. Terry, Surgeon General — Chairman

Advisory Committee on Immunization Practices

Dr. James L. Goddard, Chairman
Dr. Donald A. Henderson, Secretary
Members:
Dr. Ernest A. Ager
Dr. Gordon C. Brown
Dr. Alice D. Chenoweth
Dr. Geoffrey Edsall
Dr. David T. Karzon (unable to attend)
Dr. Theodore A. Montgomery
Dr. Roderick Murray
Dr. Paul F. Wehrle

Special Committee on Oral Poliomyelitis Vaccines - 1962

Members:
Dr. David Bodian
Dr. John P. Fox
Dr. A. L. Gray
Dr. William McD. Hammon
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SUBJECT: REPORT OF SPECIAL ADVISORY COMMITTEE ON ORAL POLIOMYELITIS VACCINE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE (JULY 17-18, 1964)

Comments by Albert B. Sabin, M.D.

I would like first of all to emphasize those portions of the report with which I am in full agreement. These are:

1) That communities which have not yet had mass campaigns should have them during the forthcoming autumn and winter (1964-1965). The mere absence of cases for several years in communities with large numbers of persons who have not had the benefit of immunization with oral poliovirus vaccine should constitute a warning of potential future outbreaks rather than a basis for complacency.

2) That special emphasis be placed on the immunization of infants during the first year of life. If this is not done on a larger scale than heretofore even communities that have already had satisfactory mass campaigns will not long continue to enjoy freedom from poliomyelitis.

3) That pending ultimate determination of the duration of immunity following oral vaccine, vaccination of all children on entry to elementary school should become a routine practice. In my opinion, they should have a single dose of trivalent vaccine if they have been previously immunized with oral vaccine and a full primary series if they have had no oral vaccine before.

The items in this report with which I disagree are concerned with the following:

1. Significance of the Very Small Number of Cases of Vaccine Associated Paralytic Disease.

It has been recognized by all (see Surgeon General's Report of September 20, 1962) that concurrent cases of paralytic disease must be expected in association with vaccination in non-epidemic areas, the expected number being lower than in epidemic areas but not zero. These concurrent cases could be expected to be composed of some that were caused by polioviruses in persons that were incubating the infection at the time they received the vaccine, some that clinically simulated poliomyelitis, but were caused by a variety of factors including other naturally occurring viruses which could be displaced from the intestinal tract by the vaccine strains that were fed. There can also be justifiable differences of opinion among

competent persons regarding the clinical diagnosis as well as judgments of compatibility as was demonstrated in my analysis of the vaccine associated cases reported in 1962 (J.A.M.A., 183:268-271, 1963). In this connection, it is noteworthy that of the 15 Type III 1962 vaccine associated cases accepted as "compatible" by the majority of the present committee, there are 4, which on the same evidence, were not accepted as "compatible" by the majority of the 1962 Public Health Service committee and 5 that were eliminated on clinical grounds by the 1962 AMA committee. It is also noteworthy that 1 of the 6 Type III, vaccine-associated cases regarded as polio-like and accepted as "compatible" in 1962 by all but one member of the PHS and AMA committees, after a lapse of more than a year developed further clinical manifestations that made the diagnosis of disseminated myelitis acceptable to all, and thus was unanimously removed from the "compatible" group. I also take exception to the third criterion for "compatibility" which calls for "laboratory data not inconsistent with respect to multiplication of the vaccine virus fed." On the basis of this criterion, Type III cases have been accepted as "compatible" when there was no laboratory work (3 cases), when no virus was isolated (13 cases), when neutralization tests were either not done (7 cases) or were inadequate (9 cases), and even when the serologic data indicated a high probability that the vaccine virus did not multiply prior to the onset of illness (5 cases).

Nevertheless, according to its own criteria for all vaccine associated cases from 1961 to 1964, the report comes up with the interesting finding that following the administration of approximately 100 million doses of each of the 3 types of monovalent vaccine, only 2 "compatible" cases were associated with Type II, 15 with Type I and 36 with Type III. While recognizing "that it is not possible to prove that any individual case was caused by the vaccines" the present report states that the above "epidemiologic" or "statistical" evidence is the basis for the belief "that at least some of these cases were caused by the vaccine" and proceeds to calculate the "extent of the risk" on the basis that all of the so-called "compatible" vaccine-associated cases were caused by the vaccines - the conclusion being that the risk is "highest" for Type III with one "compatible" case per 2.5 million doses, "less definite" for Type I with one "compatible" case per 6.25 million doses, and "suggestively absent" for Type II with one "compatible" case per 50 million doses.

The question therefore is whether one can properly take the one "compatible" case per 50 million doses of Type II vaccine as the baseline of expected concurrent incidence of polio-like paralytic disease and regard everything significantly above it as poliomyelitis caused by the vaccine viruses? In view of the very small numerators and extraordinarily large denominators and the well-known variability

in the sporadic occurrence of poliomyelitis and other polio-like paralysis, is it not possible that under different circumstances the Type II vaccine virus might also be incriminated on the same type of "guilt by association" or "guilt by statistical probability"? Actually this appears to be the situation with the 4 "compatible" cases that have occurred after the relatively small amount of trivalent vaccine that has been used thus far - Type II virus only having been recovered from 2 of these, Type I only from one and Type III only from one. If the committee is to adhere to its own criteria that the vaccine virus that is found in the stools should for purposes of evaluation be regarded as the agent responsible for the disease, 2 of the 4 trivalent vaccine "compatible" cases must be assigned to Type II. If we assume that only about 2 to 4 million doses of trivalent vaccine had been distributed up to May 1964 (and it is regrettable that commercial secrecy precludes more precise information), the occurrence of one Type II "compatible" case per 1 or 2 million doses of trivalent vaccine compared with only 1 "compatible" case per 50 million doses of monovalent Type II vaccine would constitute a highly significant statistical difference. If the committee had followed its own "epidemiologic" or "statistical" evaluation it should have concluded that the Type II vaccine virus may be responsible for some cases of paralytic disease when it is given in a trivalent mixture and not when it is given by itself. My point is that the 1 in 50 million Type II yardstick adopted as a baseline for "epidemiologic" or "statistical" incrimination of Type I or Type III oral polio vaccines as a rare cause of vaccine associated paralytic disease is unrealistic and untenable.

I believe that a separate analysis of the vaccine associated cases that occurred in 1963 and 1964 provides additional illuminating data, since, with the exception of about 2.8 million doses of Type I vaccine that were given during summer outbreaks in 1963, the remainder of the vaccine was used during the autumn, winter and spring. About 59 million doses of Type I, 54 million doses of Type II, and 76 million doses of Type III were distributed from January 1, 1963 through May 1964, and it is also evident that a considerable proportion of the 44 million doses of Type I, 39 million doses of Type II and 23 million doses of Type III that were distributed in 1962 were actually used in 1963. It is noteworthy, therefore, that by the committee's own criteria only 4 "compatible" cases occurred among an estimated 60 million persons who received the Type I vaccine in 1963 and 1964. The somewhat larger number of Type III vaccine associated cases - 16 probable and 6 "possible" cases among an estimated 76 million in 1963 and 1964 - is particularly suspect because of the unusual distribution of these cases among the sexes. Naturally occurring poliomyelitis is slightly more prevalent among males than females; in 1960, among 2,218 paralytic

cases in the U. S. A., 58% were in males and 42% in females of all ages - in the age group of 20 and over it was 59% in males and 41% in females (See U.S.P.H.S. Poliomyelitis Surveillance Report No. 234 of August 18, 1961). However, among the total group of 22 "compatible" cases (probable + "possible") following 76 million doses of Type III vaccine in 1963 and 1964 there was only one female - a 27-year old woman who had received 4 doses of Salk vaccine prior to receiving the oral vaccine. If the report were to apply the same kind of "epidemiologic" evaluation to these data, it should have concluded that the Type III vaccine is without risk for females of any age.

Another reason why I cannot accept the conclusions of this report about Type III vaccine risk - and the role of age in that risk - is contained in the 1964 results which are again different from those in 1963. After an estimated distribution of about 22 million doses of Type III vaccine from January through May, 1964, there have been only 2 probable "compatible" cases - both of them under 1 year of age. The four "possible compatible" cases constitute a particularly dubious lot as regards evidence of infection with Type III virus prior to onset of illness. In two cases there was no Type III neutralizing antibody at 31 and 32 days respectively after ingestion of the vaccine; in the third case no virus was isolated from stools obtained 18 days after the vaccine and the serologic data provided no evidence that the Type III virus had multiplied; the fourth case was clinically atypical, had a history of having received 5 doses of Salk vaccine, and there were no laboratory data.

2. Statement that Vaccine Associated Cases Occurred Largely Among Adults.

Quite aside from the fact that many of the "compatible" cases in adults are clinically dubious, the statistical analysis of estimated rates based on the Bureau of Census Survey of September 1963 (see P.S.U. No. 284, April 20, 1964), shows no particular pattern other than the unpredictable distribution of small numbers. Actually if one takes only the major groups of under 20 years and 20-49, one finds for Type I slightly more under 20 (1 in about 5.7 million) than in 20-49 (1 in about 9.5 million). For Type III, it is the reverse with 1 in about 4.4 million under 20 and 1 in about 1.9 million in the 20-49 group.

3. Statement that Unvaccinated Adults in Rural Areas and Upper Socio-Economic Groups Are at Greater Risk.

This is not borne out by an examination of the data on individual groups of "compatible" cases (e.g. Type III cases in 1963) for many of the "compatible" adult cases are in persons who have had 3 or more doses of Salk vaccine and absence of vaccination does not necessarily mean absence of naturally acquired antibody. Moreover, there is no evidence that the proportion of previously unvaccinated adults among the "compatible" cases is significantly greater than in the general population.

4. Statement that in Mass Programs the Age Groups to be Immunized Should be Determined Locally but that "the Vaccination of Individuals over School Age (18 Years) Should Generally Be Recommended Only in Those Situations in Which Unusual Exposure to Poliomyelitis Might be Anticipated....."

On the basis of the data presented above there is no good reason for adults of either sex not to avail themselves of the simple and inexpensive opportunity to be immunized against poliomyelitis. Although it is true that most adults do not need it because they are already naturally immune, there is no easy way of identifying those who are not immune. Paralytic polio is more severe and tragic in adults, and they should not rely on immunization by contact with vaccinated children or on the diminished circulation or elimination of paralytic polioviruses from their community following mass vaccination of the children.

5. Recommendation that the Order of Administration of the Monovalent Vaccines be Changed from the Present I, III, II to II, I, III.

The reason offered for this recommendation is that "giving Type II vaccine first should theoretically further diminish the slight risks associated with the other vaccine types." Examination of the available data for Type II neutralizing antibody on the Type III "compatible" cases indicates that most of them had prior immunity to Type II virus. Moreover, the 1963 experience in California where the Type III vaccine was in most instances given after the Types I and II provides no support for this recommendation. California contributed 5 of the 16 "compatible" Type III cases in 1963 - 3 of these in persons who had Types I and II vaccine before Type III and 2 in persons who had Type III as the first dose. However, one of the two latter cases, a man aged 27 years, had previously had 5 or 6 doses of Salk vaccine and had Type II neutralizing antibody, and the other (aged 18 months) had previously had 3 doses of Salk vaccine and had neither Type I nor Type II antibody.

Although there is no contraindication to giving the Type II vaccine first provided an interval of at least 8 weeks is allowed to elapse before the Type I is given, I would regard the following as objections:

a) In primary immunization of children during the first months of life when DPT and oral polio vaccine are given simultaneously the frequent 1 month interval between the doses can be expected to interfere with adequate multiplication of the Type I virus in a significant proportion of children.

b) Taking into consideration those who may not return after their first dose as well as those who will miss getting their make-up dose of trivalent vaccine at 1 year of age (especially in

clinics), the least effective procedure for providing immunity against the most prevalent Type I virus would thus be used.

c) The Public Health Service would be recommending switching to a procedure whose effectiveness in the first months of life has not been tested.

d) The recommendation for giving Type II first is inconsistent with the simultaneous recommendation of the use of trivalent vaccine, since in triple negative persons the latter usually results in the simultaneous multiplication of the Type II and III viruses.

6. Use of Trivalent Vaccine in Community Programs and for Routine Immunization.

a) Although the statement is made that monovalent vaccines are preferred for community programs, it is also stated that when certain circumstances make the use of trivalent vaccine more desirable two doses are recommended. In my opinion, two doses of trivalent vaccine should not be recommended for community programs in the U. S. A. under any circumstances because intestinal resistance to reinfection, a prime objective in community programs, can be expected to be less effective after 2 doses of trivalent vaccine, and the antibody response for Type I is inadequate in a certain proportion of triple negative persons.

b) We have no data to show that the administration of two doses of trivalent vaccine to infants at about 2 months and 4 months of age (together with the first and third doses of DPT) followed by a third dose at the end of the first year of life - particularly when many children will receive some of these doses during the summer months - will provide adequate immunization for the maximum number of infants. The available data on the high effectiveness of two doses of trivalent vaccine at an interval of 8 weeks were obtained on 6 month-24 month old children during the winter months in a northern city. Until further data become available, I would regard it as advisable that when immunization is begun at about 2 months of age with trivalent vaccine that 3 doses be given at 2 month intervals to be followed by a fourth dose at the end of the first year of life or later if breast feeding is still in progress.

c) While two doses of trivalent vaccine, 8 weeks apart, may be adequate for all persons over 1 year of age when these are given during the cold months of the year, I believe that a third dose is desirable for children living in parts of the U. S. A. with subtropical climates as well as for those who may begin their primary immunization during the warm months of the year in northern climates.

7. Lack of Positive Recommendation that Oral Polio Vaccine (OPV) is the Vaccine of Choice for Routine Immunization of Children.

Since the committee report has properly placed so much stress on the routine immunization of infants during the first year of life, it is regrettable that it has failed to bring to the attention of physicians and the public the demonstrated superiority of OPV over IPV (Salk vaccine) especially for immunization of the oncoming generations. It has been repeatedly shown that the antibody response of infants to IPV is of a low order and very often transitory. The recent demonstration of the very high effectiveness of even two doses of trivalent vaccine in producing antibodies among infants from the lowest socio-economic groups provides additional data for a positive recommendation. In addition to the above superiority in production of antibody there is the demonstrated high incidence of intestinal resistance which is most important for interfering with the circulation of virulent polioviruses in the community. Although OPV is gradually being used more and more in routine pediatric immunization by private physicians and health departments, IPV is still begin used on a large scale for such purposes - to the detriment of achieving the optimum immunization of both the individual and the community.

Paralytic Disease Associated with Oral Polio Vaccines[1]

by

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The authors wish to express appreciation to all the State epidemiologists, laboratory directors, and the many others who have cooperated to the fullest extent in the Poliomyelitis Surveillance Program and provided much of the data upon which this report is based.

Drs. Henry M. Gelfand and James H. Nakano of the Enterovirus Laboratory, Communicable Disease Center, studied many poliovirus isolates from cases included in this report. Particular attention was devoted to intratypic differentiation by means of modified Wecker and McBride tests. Considerable serological testing was also carried out. Although it is not possible to report all of these findings within the framework of this report, these data were presented to the Committee and were considered in the decisions regarding final classification of cases.

Drs. James A. Bryan, Pierce Gardner, Paul Glezen, and many other Epidemic Intelligence Service Officers participated in both the investigation of cases in the field and in the analysis of the data.

Since 1961 when the oral poliomyelitis vaccines were first made available for general use in the United States, scattered cases of paralytic disease have occurred in association with these vaccines. Many of the cases have been clinically indistinguishable from poliomyelitis. Epidemiologically, the pattern of their occurrence has raised the possibility that some may have been caused by the vaccine.

In 1962 when the existence of this problem was first appreciated, the Surgeon General of the Public Health Service convened a Special Advisory Committee which met on a number of occasions between August and December. The Committee reviewed in detail reported cases of paralytic disease occurring within a period of 30 days following ingestion of the oral poliomyelitis vaccines. The Committee concluded that 18 cases of paralytic poliomyelitis were "compatible with the possibility of having been induced by the vaccine".[1] Of these, 11 followed Type III vaccine and 7 followed Type I vaccine. The Committee concluded that "the maximum potential risk for Types I and III vaccine is of the order of one per million or less overall; but higher for those over 30 years of age." The Committee recommended "that community plans for immunization be encouraged" but "because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adults only with the full recognition of its very small risk."

Following this report, additional community-wide programs employing oral poliomyelitis vaccines have been conducted in many parts of the country, especially in urban areas. By May 1964, about 100 million doses of each of the 3 types of vaccine had been distributed plus several million doses of oral trivalent vaccine. Additional cases of paralytic poliomyelitis associated with the administration of the oral vaccine have been reported. The total number of such reports received by the Public Health Service through June 1964 is 123. This number includes those cases reviewed by the Committee in 1962. Of this total, 36 cases occurred in epidemic areas where mass immunization programs were undertaken as emergency control measures. The remaining 87 cases were widely scattered and occurred in non-epidemic areas usually following community-wide oral poliomyelitis vaccination programs.

Because of this continued incidence of vaccine associated cases, a Committee* was again convened by the Surgeon General to re-assess the problem and to develop recommendations for the future use of oral poliomyelitis vaccines. The Committee met on July 17-18, 1964.

The report of the Committee is published elsewhere in this issue.[2] The present paper summarizes the basic epidemiological information that was considered by the Committee in arriving at its conclusions and in making its recommendations.

* Members of the Committee are: Dr. Luther L. Terry, Surgeon General, Chairman; Dr. James L. Goddard, Dr. Donald A. Henderson, Dr. Ernest A. Ager, Dr. Gordon C. Brown, Dr. Alice D. Chenoweth, Dr. Geoffrey Edsall, Dr. David T. Karzon, Dr. Theodore A. Montgomery, Dr. Roderick Murray, Dr. Paul F. Wehrle, Dr. David Bodian, Dr. John P. Fox, Dr. A. L. Gray, Dr. William McD. Hammon, Dr. Alexander D. Langmuir, Dr. Albert Sabin, and Dr. Edward B. Shaw.

Sources of Data and Classification of Cases

The Poliomyelitis Surveillance Unit of the Communicable Disease Center receives case reports from State and local health departments through the National Morbidity Reporting System. In addition, since 1958, individual surveillance forms have been submitted for each case, a preliminary form which supplies basic epidemiologic data, and a follow-up form which includes information regarding extent of residual paralysis of the case plus results obtained in laboratory studies. The incidence of cases of poliomyelitis with residual paralysis at 60 days represents the most reliable index presently available to assess, on a continuing basis, the national status of poliomyelitis.(3)

Since December, 1961, 123 cases of paralytic poliomyelitis have been reported which occurred less than 30 days after administration of the oral poliomyelitis vaccines. These were scrutinized with greater care. Detailed clinical and epidemiological information regarding these cases was obtained. Many were examined by special consultants. Virological and serological specimens were studied intensively.

Of the 123 vaccine associated cases, 36 occurred in epidemic areas in conjunction with emergency vaccine feeding programs. Most undoubtedly were in the incubation period of a naturally acquired infection at the time of feeding. The remaining 87 cases occurred in non-epidemic areas; they were widely scattered throughout the country. These latter cases received particular attention.

The Advisory Committee reviewed all available information pertaining to each of the 87 vaccine associated cases which had occurred in

non-epidemic areas. The cases were classified into one of three categories with respect to possible relationship to vaccine administration:

1. "Compatible"
2. "Uncertain"
3. "Excluded"

The cases were classified as "compatible" if they met the following criteria:

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine type in question and with an onset of paralysis not sooner than 6 days after the feeding.
2. Significant residual lower motor neuron paralysis.
3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.
4. No evidence of: (a) upper motor neuron disease, (b) definite sensory loss, or (c) progression or recurrence of paralytic illness one month or more after onset.

Cases not meeting these criteria were designated "excluded" with respect to the question of significant residual paralytic illness related to vaccine administration. Those for whom the data were considered insufficient upon which to base a judgment were placed in the category of "uncertain".

The "compatible" cases were further subdivided into "probable" and "possible" categories employing as guidelines for the "probable" cases:

1. Evidence of fever at onset of paralysis.
2. History of systemic illness preceding the development of paralysis.
3. Clinical evidence of meningeal involvement manifested either by nuchal rigidity or cerebrospinal fluid cell count greater than 10 cells per cubic milliliter.

Cases in the "possible" category lacked one or more of these criteria, frequently for want of adequate observation at the time of the acute illness.

Poliomyelitis Incidence

Progress in the control of poliomyelitis in the United States is depicted in Figure 1. The decline in annual incidence during the past 10 year period has been marked. The average annual rate for paralytic cases for the period 1950-54 was 14.6 per 100,000 population, compared with an average rate of 0.4 for the 3 year period 1961-63. The occurrence of poliomyelitis by four-week periods since 1961 is shown in Figure 2 on a greatly expanded scale. The absence even of a seasonal summer rise in incidence in 1964 is notable.

Throughout this recent period there were no epidemics comparable in size to many observed in past years. The largest outbreak since 1962 occurred in Texas and involved a number of different communities in many parts of the State; 174 cases were reported. The location and extent of the outbreaks of poliomyelitis in the country during 1962 and 1963 is portrayed in Figures 3 and 4 and in Table 1. "Epidemic areas" are defined as those areas reporting 6 or more paralytic cases of

which at least 4 occurred within a 30-day period. During the past two years, a total of 16 outbreaks in 13 States were recorded. All were caused by Type I poliovirus. In 13 of these 16 outbreaks, mass immunization programs were conducted in an effort to abort the epidemics. No outbreaks have been observed during the first 8 months of 1964.

The epidemic areas in 1962 accounted for 304 of the 691 reported cases with residual paralysis. In 1963, 137 of the 331 cases occurred in epidemic areas (Table 2). In both epidemic and non-epidemic areas, cases were predominantly in the younger age groups, approximately half being under 5 years of age. A somewhat higher proportion of adult cases was recorded in non-epidemic areas.

As shown in Table 3, Type I poliovirus was the most prevalent type in both epidemic and non-epidemic areas. All outbreaks were due to Type I infection, although in 1962, 24 scattered Type III cases were also identified in these areas. In the non-epidemic areas, Type III accounted for approximately 35 percent of the laboratory confirmed cases in 1962 and 30 percent in 1963. In the first half of 1964, Type III poliovirus accounted for 11 of the 22 isolates.

Vaccine Associated Cases

Of the 123 cases of paralytic poliomyelitis occurring less than 30 days after oral vaccine administration, 87 were reported from non-epidemic areas, 36 from epidemic areas.

Non-epidemic Areas: Of the 87 non-epidemic area cases, the Advisory Committee categorized 57 as being "compatible" with vaccine-induced disease (Table 4). Fifteen followed Type I vaccine, 2 followed Type II,

36 followed Type III and 4 followed trivalent vaccine. There were 9 cases classified as "uncertain" and 21 cases were placed in the "excluded" category.

All of the 57 "compatible" cases had significant residual paralysis, this being a basic requirement for classification as a "compatible" case. There were 2 deaths, one followed Type III vaccine and one trivalent vaccine administration. Histological examination revealed acute anterior horn cell disease in both, although the immediate cause of death in one was considered to be the result of a pulmonary embolus.

The 57 "compatible" cases were reported from 49 counties in 24 States; 41 of the cases represented the only cases reported from their respective counties during the past two and one half years. A small concentration of "compatible" cases were observed in the San Francisco Bay area, 5 cases resident in 4 counties occurred between October 1 and November 6, 1962, less than 30 days after a Type I community vaccine program. In these counties during 1962, 6 other cases of poliomyelitis were reported.

In Nebraska, 8 cases occurred in 7 different counties between July 1 and September 3, 1962, less than 30 days following the administration of Type III oral vaccine. Except for vaccine associated cases, no other poliomyelitis cases were reported in Nebraska during 1962. An intensive State-wide search for possible non-vaccine related cases revealed a number of records of aseptic meningitis, infectious polyneuritis and other neurological diseases but no additional cases of paralytic poliomyelitis.(4)

In North Carolina, 3 cases among residents in 3 separate counties, occurred between March 7 and April 7, 1964, within 30 days after trivalent vaccine ingestion. One other case of poliomyelitis was reported in North Carolina during the first 6 months of 1964.

Intensive laboratory studies were conducted on many of these "compatible" cases. Polioviruses were isolated from a high proportion; in essentially all instances the type of virus identified was the same as the type last fed prior to onset of illness. Because of recent vaccine ingestion the diagnostic significance of the isolates was problematic except to indicate that proliferation of the vaccine virus had taken place. In many cases intensive studies were conducted in an effort to identify a possible infection with certain of the enteroviruses or other pathogens such as arboviruses that may sometimes cause paralytic illnesses. In none of the "compatible" cases did these suggest a diagnosis other than poliomyelitis.

The vaccine administered to the "compatible" cases was provided by several manufacturers and involved many different production batches and filling lots. In each of the 3 geographic clusters, two or more lots of vaccine were involved and in 2 of the clusters, vaccine from 2 or more manufacturers was given to "compatible" cases.

The history of previous immunization of the "compatible" cases with inactivated poliomyelitis vaccine is summarized in Table 5. Two-thirds of the cases had received no inactivated vaccine. Ten had received four or more injections.

Epidemic Areas: Thirty-six cases of paralytic poliomyelitis were reported from epidemic areas which occurred less than 30 days after oral vaccine administration. Since these cases occurred in areas where naturally occurring strains were demonstrably present and since many of the cases undoubtedly were incubating these strains at the time of feeding, the Advisory Committee did not attempt to appraise this group of cases with respect to "compatibility" with vaccine induced disease. Surveillance data did indicate that all of these cases had residual paralysis 60 days after onset of infection.

Of the 36 cases, 34 followed administration of Type I vaccine and 2 followed administration of Type III vaccine. The vaccine associated epidemic area cases occurred during eight of the outbreaks noted in Table 1. As previously noted, all recent outbreaks in this country have been caused by Type I poliovirus; Type I oral polio vaccine has been employed as a control measure. Thus, the occurrence of vaccine associated cases with types other than Type I would be exceptional. The two cases which occurred following Type III vaccine administration were reported from Texas during the epidemic period; both were adults.

Contrast of Epidemiological Patterns: The age and sex distributions of the "compatible" and epidemic area vaccine associated cases are compared in Table 6. "Compatible" cases are sharply concentrated among adults; 44 or 77 percent are 15 years of age and older; of the epidemic area cases, only 6 or 17 percent are 15 years or older. Of the 57 "compatible" cases, 46 or 80 percent are males, whereas the two sexes are represented equally among the epidemic area cases.

The intervals from dates of vaccine administration to dates of onset of first symptoms are presented in Figure 5. The epidemic area cases tend to occur soon after vaccine ingestion; 27 of the 36 cases occurred less than 12 days after vaccination. The 9 cases with intervals greater than 12 days occurred in Texas during the 1962 epidemic. Included in this group are the 2 Type III cases previously mentioned.

The intervals following vaccine administration among the "compatible" cases tend to fall in the period, 7 to 21 days. Parenthetically, however, it should be noted that the criteria for designating a case to be "compatible" required that at least four days must have elapsed between vaccine feeding and onset of illness. Among the 21 cases reviewed by the Committee which were not placed in the "compatible" category, there were two cases with intervals between administration of vaccine and onset of illness of between 0 and 3 days.

Relative Frequency of "Compatible" Cases: The incidence of "compatible" and total cases in children and adults by quarter-year periods from January 1962 to June 1964 is shown in Table 7. Although there has been a marked decline in the incidence of total cases over this time span, the frequency of "compatible" cases has not declined proportionately. Among children the relative frequency of "compatible" cases to the total was about 2 percent in 1962 and 1963. This rose somewhat during the first half of 1964, although because of the small numbers of cases involved, this increase may not be significant. Among the adults in 1962, 19 percent of the total cases were "compatible". In 1963, this proportion rose to 33 percent, and in 1964, 10 of 14 cases or 71 percent were "compatible".

Use of the Vaccine

Complete records of vaccine utilization in the nation are not available but reasonable estimates may be made from data supplied by the commercial firms to the Biologics Surveillance Unit, CDC, regarding vaccine distribution. These data are presented in Table 8.

Since licensure of the monovalent vaccines through May 1964, 104 million doses of Type I have been distributed; 93 million doses of Type II and 99 million doses of Type III. In addition, several million doses of trivalent vaccine have been utilized recently, predominantly in physicians' offices and to a limited extent in community programs. The greatest use of the monovalent vaccines has been in community immunization programs. Most such programs included all age groups in the community; a few were limited to younger children.

Of the total amount of vaccine distributed, a proportion of the vaccine would not have been administered because of normal vaccine "wastage". In a number of community programs "wastage" represented as much as 15 to 30 percent of the available supply. Overall, it is estimated that at least 10 percent of vaccine distributed was not actually administered because of this "wastage" factor.

The proportionate distribution of vaccine by age group can be approximated from two sources of data. In September 1963, through the random sample survey of 35,000 households conducted by the Bureau of the Census, a question regarding the number of doses of oral vaccine received was asked of all individuals up to 50 years of age. For those over 50, an estimate of participation can be derived from data available

from community vaccination programs. While different programs varied in the extent of their coverage, surveys throughout the nation revealed that all age groups, particularly the adults, responded remarkably well.

Based on the data of vaccine distribution and the proportionate distribution of vaccine by age, an estimate has been made of the total amounts of Type I and III vaccine administered through May 1964, by age, in non-epidemic areas (Table 9). Relating the "compatible" cases to these estimates, the extent of the risk has been estimated per million doses of vaccine administered.

The overall rate for Type I vaccine is 0.17 per million doses fed; for Type II, 0.02; for Type III, 0.40. The rates vary quite markedly by age. In the age group under five, 6 cases followed Type III vaccine giving an estimated rate of 0.53 per million doses; 2 cases followed Type I in this age group for a rate of 0.19. In the 5 to 14 year age group, the rates for both vaccines are below 0.10. In the older age groups, the rates are higher, particularly for Type III vaccine; among those 15 to 39, the rate is 0.64 per million doses fed or one case per 1.6 million doses administered.

Cases Among Household Contacts

Throughout the period since first licensure of oral poliomyelitis vaccine, a careful surveillance has been maintained for cases of poliomyelitis developing among unvaccinated household contacts. The frequency of such cases has been low. Two contact cases, one in an 18 month old child, the other in a 29 year old male, have been reported within 30 days after primary vaccine administration. Both were household

contacts of Type III vaccinees. An additional case occurred in a 6 month old child, who was known to have been in close association with other children who were fed Type III vaccine.

Discussion and Summary:

In the United States the incidence of paralytic poliomyelitis has declined precipitously in recent years. The number of cases recorded during 1963 was 331, only 48 percent of the total in 1962, which was itself a record low year. In 1964, through June, reported cases were less than half as frequent as in 1963. Epidemics of poliomyelitis as previously known have disappeared; outbreaks have become infrequent and localized.

A cause for concern, however, has been the continuing occurrence of cases of paralytic disease in association with the administration of the oral poliomyelitis vaccines. Reported since December 1961 have been 123 vaccine associated cases. The epidemiological characteristics of 36 of these cases, which occurred in conjunction with vaccine control programs in epidemic areas, were such as to suggest that most were in the incubation period of a naturally acquired infection at the time of feeding.

The 87 vaccine associated cases from non-epidemic areas were of greater concern and were scrutinized more carefully. Fifty-seven were adjudged by the Committee to be clinically indistinguishable from paralytic poliomyelitis; all had significant residual paralysis; their onsets occurred between 4 and 30 days after feeding and laboratory data

were not inconsistent with respect to multiplication of the vaccine fed. These cases differed significantly in their epidemiologic characteristics from those in epidemic areas. The cases were widely scattered throughout the country and in most instances were the only cases of poliomyelitis to be reported in their respective counties. The interval from vaccine ingestion to onset of illness peaked in the range of 7 to 21 days.

The Advisory Committee concluded "that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests available can provide a definitive answer. Nevertheless, considering the epidemiological evidence developed with respect to the total group of compatible cases, the Committee believes that at least some of these cases were caused by the vaccine."

The extent of the risk associated with the separate monovalent vaccine types was notably different. The rate per million doses fed was 0.40 for Type III and 0.02 for Type II; Type I was intermediate between these with a rate of 0.17 per million doses administered. With respect to Type III vaccine, the risk was significantly greater among adults than among children; for Type I vaccine, there were no appreciable differences by age.

Further definition of the risk in various population groups was not possible although certain groups did appear to be at greater risk than others. For example, the number of cases following Type III vaccine in adults was considerably higher among males than females. In recent years, naturally occurring infections among adult males have become proportionately more frequent rising from less than 50 percent

of the adult cases in 1955[5] to over 60 percent recorded during the past three years.[6] The immunization status of adult males with respect to inactivated vaccine has been demonstrably poorer than for that for females.[7] Further, their opportunity for exposure to young children and, thereby, natural infection is less. They thus would appear to constitute a more susceptible group. Other susceptible groups would be those residing in rural areas and those from upper socioeconomic groups who have less opportunity for exposure to naturally spreading polioviruses. Although it was not possible to quantitate the relative frequency of vaccine associated cases among such groups, there did appear to be a higher frequency of occurrence of vaccine associated cases among those residing in the more rural areas and those in the upper socioeconomic groups.

Particularly notable is the increasing rarity of naturally occurring paralytic poliomyelitis among adults. In 1963, of 42 cases among persons 15 years and over, only 28 represented non-vaccine associated cases; during the first 6 months of 1964, only 4 cases of a reported 14 cases of paralytic poliomyelitis in this age group were non-vaccine associated.

Despite the administration of large amounts of vaccine in community programs, some of which included children only, vaccine associated cases among contacts have been infrequent. Prior to general vaccine use, concern was expressed that there might be mutant strains transmitted from vaccinees to non-vaccinees which would induce disease in the contacts.[8] This has not proved to be a significant problem.

With these considerations in mind, the Advisory Committee recommended "changes in emphasis" of the national poliomyelitis program stressing continuing intensive immunization of infants and preschool age children, the groups demonstrably at greatest risk of naturally acquired infection and the principal disseminators of the natural infection within the community.

Table 1

Outbreaks of Paralytic Poliomyelitis
United States: 1962-1963

Epidemic Areas*	Paralytic Cases	1960 Population	Type I OPV Estimated No. of Doses Fed
1962			
Mobile County, Alabama	10	314,301	280,000
Washington County, Arkansas	6	55,797	37,000
Los Angeles County, California	38	6,038,771	2,801,000
Cook County, Illinois	40	5,129,725	None
Northeast Kentucky (Includes Boyd, Fleming, Greenup, and Mason Counties)	12	110,745	15,000
Northeast Oklahoma (Includes Creek, McIntosh, Muskogee, Tulsa, and Washington Counties)	14	503,117	150,000
Texas (Entire State)	174**	9,579,677	3,600,000
Fayette County, West Virginia	10	61,731	None
1963			
Northwest Alabama (Includes Lawrence, Winston Marion and Walker Counties)	21	115,407	80,000
Duval County, Florida	24	455,411	420,000
Lowndes County, Georgia	7	49,270	None
Kent County, Michigan	6	363,187	348,000
Metropolitan Philadelphia, Pa. (Includes Philadelphia, Chester, Delaware, Bucks and Montgomery Counties, Pa.; Burlington, Camden and Gloucester Counties, N.J.)	43	4,342,897	1,500,000
Luzerne County, Pennsylvania	8	346,972	275,000
Cumberland and Perry Counties, Pennsylvania	15	151,398	77,000
Petersburg, Virginia	13	113,650	103,000

* Areas with 6 or more paralytic cases; at least 4 occurring within a 30-day period.

** Includes 2 California cases imported from Texas.

Table 2

Reported Cases of Poliomyelitis With
Residual Paralysis in the United States
Age by Epidemic and Non-Epidemic Areas
1962, 1963, 1964 (Through June)

1962

Age Group	Number of Cases: Epidemic Areas	Non-Epidemic Areas	Total
0-4	176	165	341
5-9	65	75	140
10-14	24	48	72
15-19	8	18	26
20-29	15	36	51
30-39	11	27	38
40+	5	18	23
TOTAL	304	387	691

1963

Age Group	Number of Cases: Epidemic Areas	Non-Epidemic Areas	Total
0-4	72	94	166
5-9	25	35	60
10-14	18	20	38
15-19	5	10	15
20-29	9	16	25
30-39	5	14	19
40+	3	5	8
TOTAL	137	194	331*

Table 2 (Cont.)

1964**

Age Group	Number of Cases: Epidemic Areas	Non-Epidemic Areas	Total
0-4	-	15	15
5-9	-	3	3
10-14	-	3	3
15-19	-	3	3
20-29	-	1	1
30-39	-	4	4
40+	-	6	6
TOTAL	-	35	35

* Includes two cases unofficially reported (4 and 39 years of age).
** 1964 cases reported through August 15 with onsets through June 27, 1964.

Table 3

Poliovirus Types Isolated in Epidemic and Non-Epidemic Areas
From Cases of Poliomyelitis With Residual Paralysis
1962, 1963 (Through June)

Year	Epidemic Areas					Non-Epidemic Areas				
	Total Cases	Total Spec.	Poliovirus Isolated I	II	III	Total Cases	Total Spec.	Poliovirus Isolated I	II	III
1962	304	200	166	0	24	387	272	136*	8	76*
1963	137	104	93	0	0	194	134	66	5	31
1964**	0	-	-	-	-	35	28	9	2	11

* Includes double isolation of types I and III from two individuals.

** 1964 cases include those reported through August 15 with onsets through June 27, 1964.

Table 4

Paralytic Poliomyelitis Occurring in Association With Oral Poliomyelitis Vaccines in Non-Epidemic Areas Categorizations by Advisory Committee With Respect To Vaccine Relationship; December 1961 - June 1964

Type Vaccine Administered	Year	Categorization by Advisory Committee		
		Compatible	Uncertain	Excluded
Type I	1961	2 (2)	0	0
	1962	9 (7)	4	5
	1963	2 (2)	0	3
	1964	2 (2)	0	0
	Total	15 (13)	4	8
Type II	1962	1 (1)	0	5
	1963	0	0	0
	1964	1 (0)	0	0
	Total	2 (1)	0	5
Type III	1962	15 (11)	1	8
	1963	16 (13)	2	0
	1964	5 (2)	2	0
	Total	36 (26)	5	8
Trivalent	1964	4 (2)	0	0
Grand Total		57 (42)	9	21

Table 5

Compatible Cases* by Broad Age Group and IPV Status
December 1961 - June 1964

OPV	Age Group	Doses of Inactivated Poliomyelitis Vaccine 0	1-2	3	4+	Unk.	Total
I	<15	0	1	1	2	0	4
	15+	7	1	0	1	2	11
II	<15	0	0	1	0	0	1
	15+	1	0	0	0	0	1
III	<15	4	0	3	1	0	8
	15+	19	0	0	6	3	28
Tri.	<15	0	0	0	0	0	0
	15+	4	0	0	0	0	4
Total	<15	4	1	5	3	0	13
	15+	31	1	0	7	5	44
	Total	35	2	5	10	5	57

* Cases considered compatible by Advisory Committee

Table 6

Age and Sex Distribution of Vaccine Associated Cases of Poliomyelitis; "Compatible" Cases in Non-Epidemic Areas and Cases with Residual Paralysis in Epidemic Areas December 1961 - June 1964

Age Group	"Compatible" Cases			Epidemic Area Cases		
	M	F	Total	M	F	Total
0-4	6	2	8	10	11	21
5-9	2	1	3	3	3	6
10-14	0	2	2	2	1	3
15-19	7	1	8	0	0	0
20-29	6	1	7	1	1	2
30-39	12	1	13	2	0	2
40-49	7	1	8	1	1	2
50+	6	2	8	0	0	0
Total	46	11	57	19	17	36

Table 7

Reported Cases of Poliomyelitis With
Residual Paralysis and Vaccine Associated
Paralytic Poliomyelitis Categorized as "Compatible"*
By Quarter-Year Period and Broad Age Group
Non-Epidemic Areas
January, 1962 - June, 1964

Year	Weeks** of Onset	Under 15 Years			15+ Years		
		Total Cases	"Compatible" Cases	Percent "Compatible"	Total Cases	"Compatible" Cases	Percent "Compatible"
1962:	1-13	21	1		8	0	
	14-26	34	0		15	4	
	27-39	160	2		54	10	
	40-52	59	3		21	5	
	TOTAL	274	6	2.2%	98	19	19.4%
1963:	1-13	18	1		10	6	
	14-26	24***	2		12***	5	
	27-39	81	0		13	0	
	40-52	24	1		7	3	
	TOTAL	147	4	2.7%	42	14	33.3%
1964:	1-13	6	1		10	6	
	14-26	15	1		4	4	
	TOTAL	21	2	9.5%	14	10	71.4%

* Categorized "compatible" by Special Advisory Committee.

** Does not include 20 cases with unknown onset.

*** Includes a "compatible" case not yet officially reported.

Table 8

Estimated Annual Distribution of Oral Poliomyelitis Vaccine*
From Date of Licensure Through May, 1964
(Thousands of Doses)

Year	Type I		Type II		Type III	
	Annual	Cumulative	Annual	Cumulative	Annual	Cumulative
Licensure:	August 17, 1961		October 6, 1961		March 27, 1962	
1961	587	587	151	151		
1962	44,568	45,155	39,379	39,530	22,687	22,687
1963	38,731	83,886	34,227	73,757	54,206	76,893
1964**	20,101	103,987	19,696	93,453	21,945	98,838

* Sources of Distribution Data:
January 1960-June 1962: State Health Departments and PHS Regional Offices
July 1962-May 1964 : Biologic Surveillance Unit, CDC

** Through May

Note: All figures should be considered estimates.

Table 9

Estimated Incidence Rates by Age Group
"Compatible" Cases Associated With Oral Vaccine Administration

Age Group	Proportion[1] of Vaccine Received	Estimated[2] Vaccine Received (000's of doses)	Number[3] "Compatible" Cases	Cases Per Million Doses
Type I				
0-4	12.63	10,719	2	0.19
5-9	16.36	13,885	1	0.08
10-14	14.66	12,442	1	
15-19	9.98	8,470	4	
20-29	11.79	10,006	1	0.24
30-39	13.25	11,245	2	
40-49	11.33	9,616	1	
50 +	10.00	8,487	3	0.22
Total	100.00	84,870	15	0.17
Type III				
0-4	12.63	11,235	6	0.53
5-9	16.36	14,553	1	
10-14	14.66	13,041	1	0.07
15-19	9.98	8,878	4	
20-29	11.79	10,488	6	0.64
30-39	13.25	11,786	10	
40-49	11.33	10,078	3	
50 +	10.00	8,895	5	0.42
Total	100.00	88,954	36	0.40

[1]Based on Bureau of Census Survey, September, 1963 (See PSU #284, April 20, 1964). Vaccine status queried for individuals 0-49 years of age. Minimum estimate for 50+ age group based on selected community-wide programs for which survey or complete tabulations were known for the 50+ age group.

[2]Estimates of total use derived by deducting 10 percent as "wastage" estimate from total vaccine distributed in non-epidemic areas (Type I: 9,686,000 doses) from date of licensure through May 1964.

[3]Categorization made by Special Advisory Committee.

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2.

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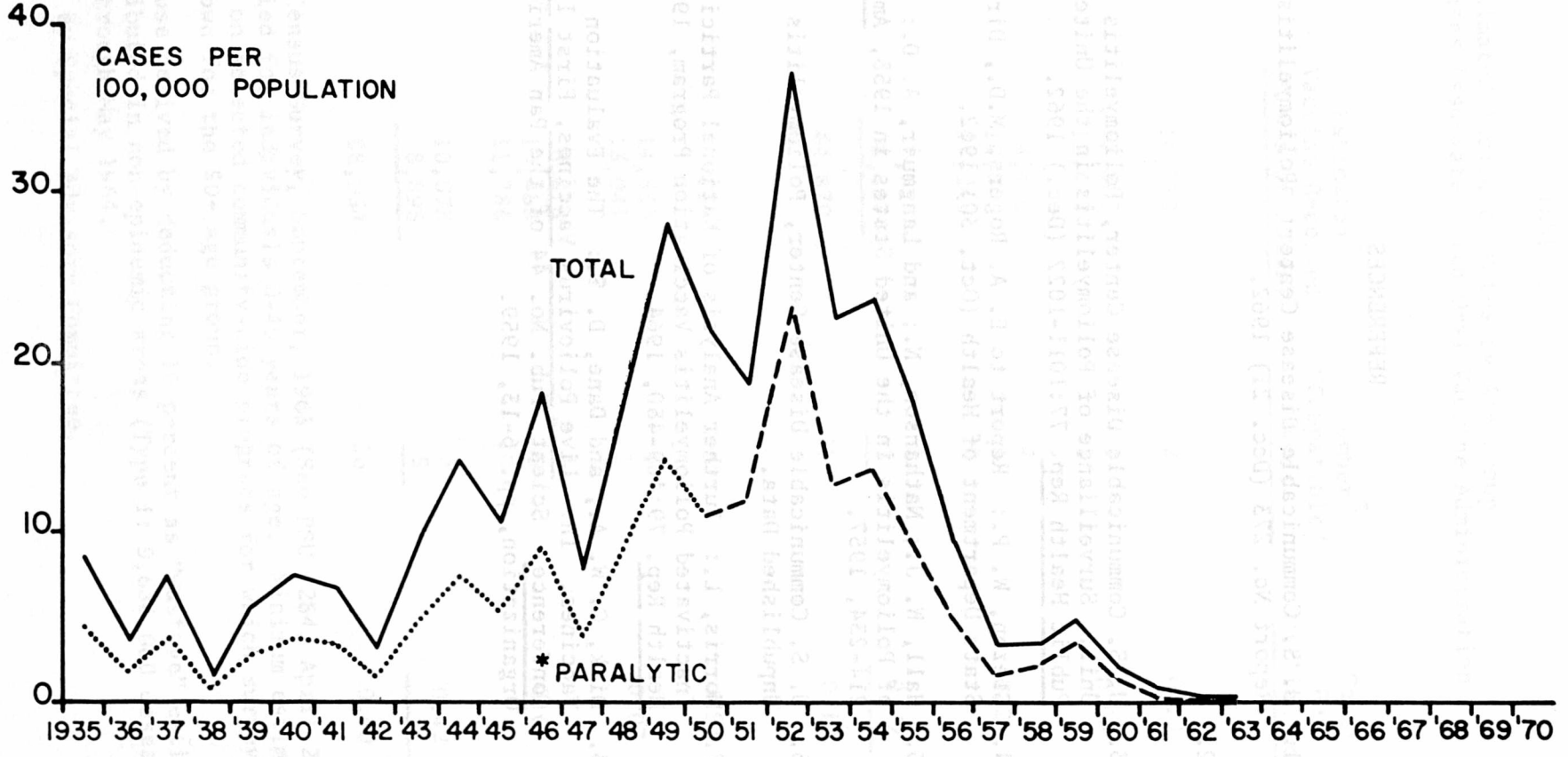
Figure 1

ANNUAL POLIOMYELITIS INCIDENCE RATES
UNITED STATES, 1935-1963



* PARALYTIC CASES PRIOR TO 1951 ASSUMED TO BE 50% OF TOTAL. SINCE 1951, CASES REPORTED AS UNSPECIFIED WERE PRORATED AMONG PARALYTIC AND NONPARALYTIC CASES.

Figure II

PARALYTIC POLIOMYELITIS REPORTED TO POLIOMYELITIS SURVEILLANCE UNIT

1961-1963: BY DATE OF ONSET
1964: BY DATE OF REPORT

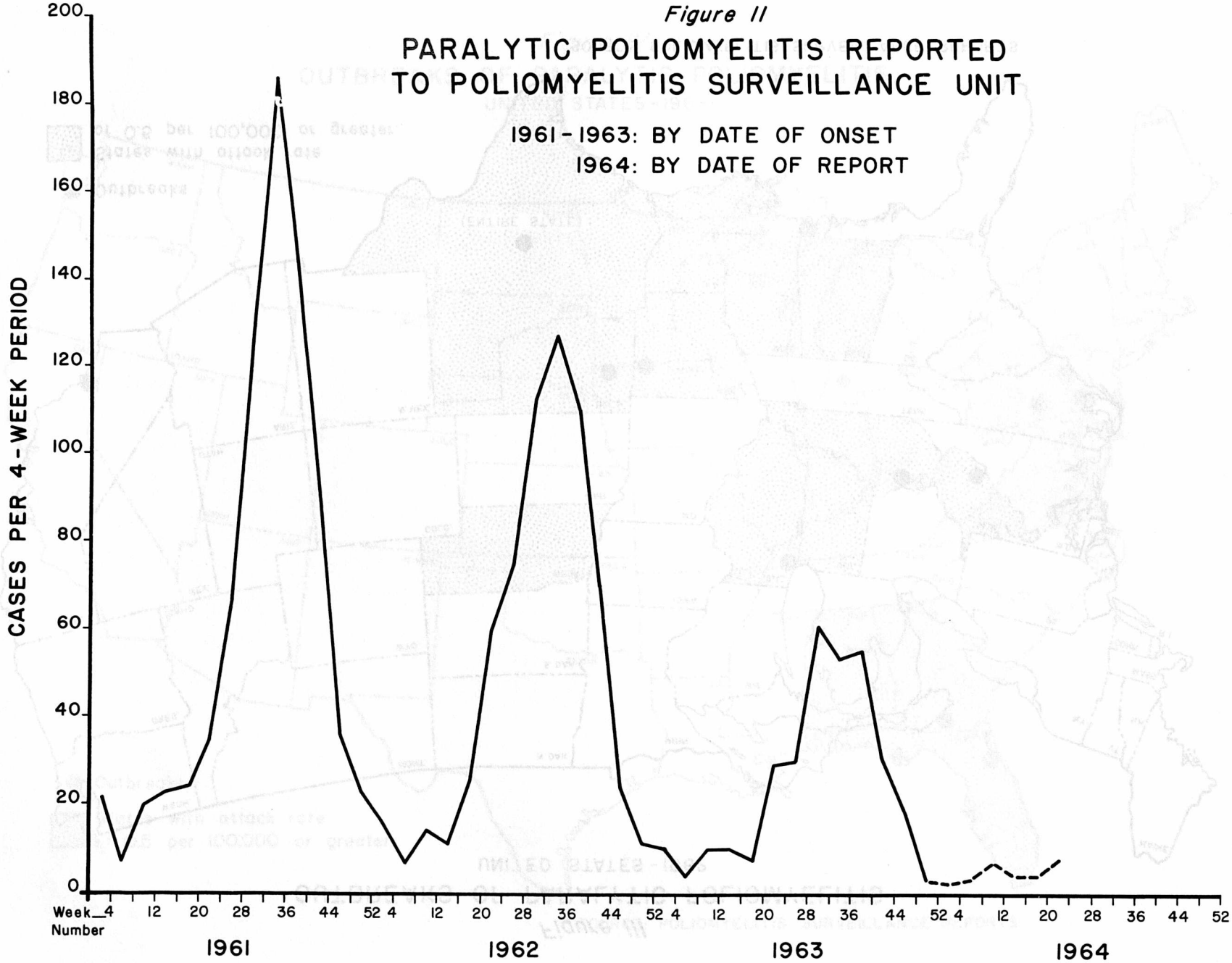
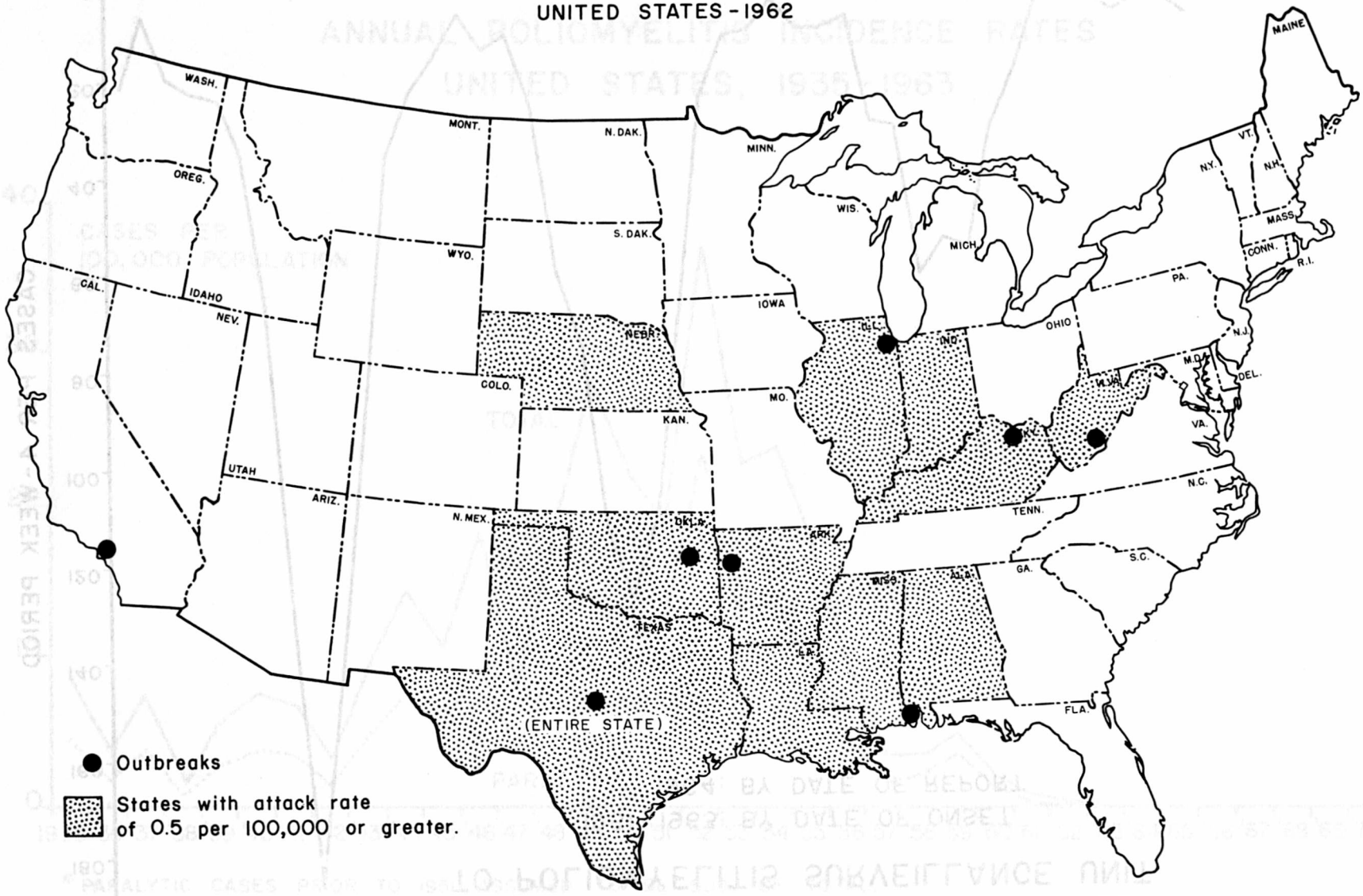


Figure III

OUTBREAKS OF PARALYTIC POLIOMYELITIS

UNITED STATES - 1962

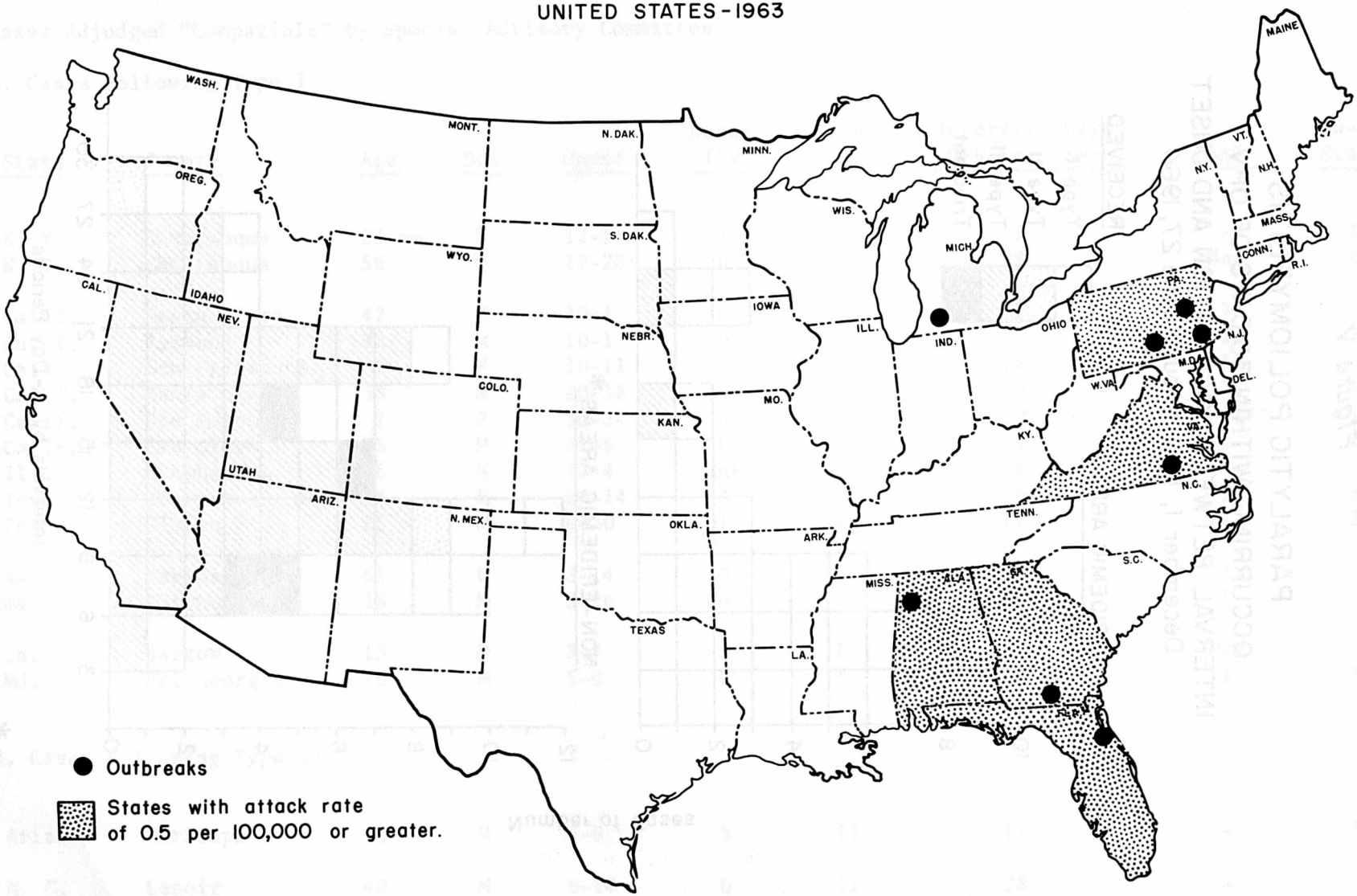


SOURCE: POLIOMYELITIS SURVEILLANCE REPORTS

Figure IV

OUTBREAKS OF PARALYTIC POLIOMYELITIS

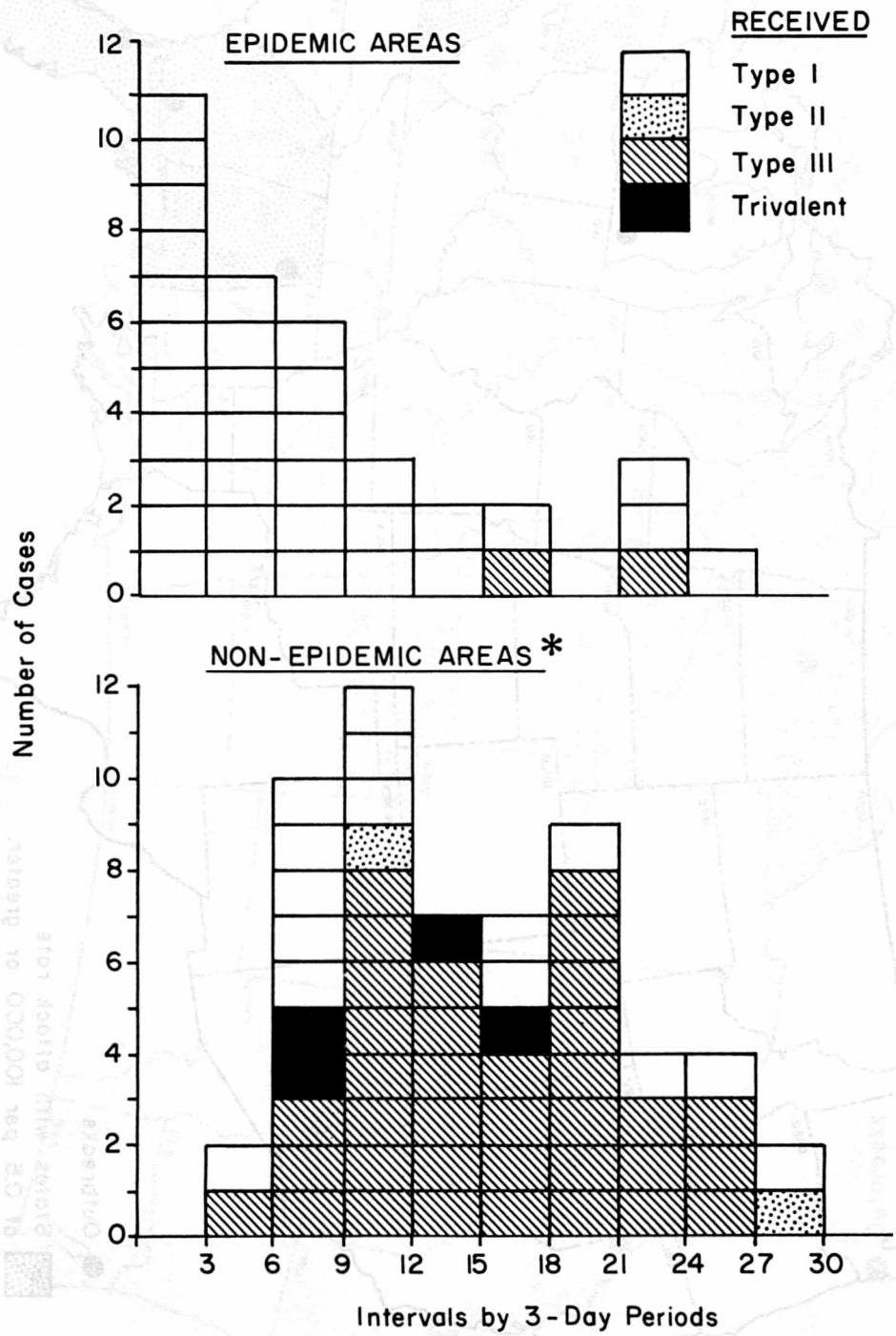
UNITED STATES - 1963



SOURCE: POLIOMYELITIS SURVEILLANCE REPORTS

Figure V

PARALYTIC POLIOMYELITIS
OCCURRING WITHIN 30 DAYS OF OPV
INTERVAL BETWEEN VACCINATION AND ONSET
December 1, 1961 through June 27, 1964



*Cases considered compatible by committee

Paralytic Poliomyelitis Cases (Non-Epidemic Areas)
With Onsets Less than 30 Days After Receiving OPV

I. Cases Adjudged "Compatible" by Special Advisory Committee

A. Cases Following Type I

	State	County	Age	Sex	Onset	Doses IPV	Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
1961										
	N. Y.	Chautauqua	23 mo.	F	12-16	4	I	7	-	3
	N. Y.	Chautauqua	56	M	12-28	0	I	28	Neg.	4
1962										
	Calif.	Santa Clara	42	M	10-1	0	I	8	I	4
	Calif.	Alameda	32	M	10-1	0	I	7	I	3
	Calif.	San Francisco	2	F	10-11	2	I	18	I	3
	Calif.	Santa Clara	58	M	10-18	0	I	25	I	3
	Calif.	San Mateo	7	F	10-24	6	I	22	II**	2
	Calif.	San Diego	35	M	11-6	0	I	9	I	3
	Ill.	Stephenson	16	M	10-4	Unk	I	4	I	3
	Iowa	Story	14	F	10-14	3	I	9	I	3
	Tenn.	Gibson	25	M	8-30	1	I	10	I	3
1963										
	Wash.	Yakima	61	F	3-14	0	I	11	I	2
	Wisc.	Chippewa	18	M	3-26	Unk	I	10	I	3
1964										
	Ga.	Bartow	15	M	3-5	5	I	25	Neg.	3
	Md.	Pr. Georges	15	M	5-9	0	I	20	I	3

B. Cases Following Type II

1962										
	Ariz.	Maricopa	6	M	3-9	3	II	12	-	3
1964										
	N. C.	Lenoir	49	M	6-14	0	II	28	-	

C. Cases Following Type III

	State	County	Age	Sex	Onset
1962					
	Mich.	Branch	23	M	7-15
	Mich.	Midland	36	F	7-20
	Neb.	Douglas	18	F	7-1
	Neb.	Douglas	51	M	7-16
	Neb.	Dodge	37	M	7-23
	Neb.	Lancaster	6	M	8-5 or 8-1
	Neb.	Cherry	55	M	8-15
	Neb.	Phelps	50	F	8-16
	Neb.	Lincoln	57	M	8-24
	Neb.	Keya Paha	13	F	9-3
	Ohio	Portage	16	M	6-8
	Ohio	Cuyahoga	36	M	7-18
	Okla.	Logan	33	M	8-7
	Oreg.	Washington	48	F	5-5
	Oreg.	Benton	52	M	6-26
1963					
	Calif.	Sacramento	39	M	1-24
	Calif.	Los Angeles	30	M	3-1
	Calif.	Napa	39	M	3-23
	Calif.	Shasta	1 1/2	M	3-26
	Calif.	Los Angeles	27	M	12-10
	Mass.	Middlesex	21	M	5-28
	Mass.	Middlesex	27	F	6-7
	Minn.	Hennepin	19	M	5-27
	Pa.	Schuykill	30	M	6-8
	Pa.	Delaware	39	M	11-21
	Pa.	Delaware	47	M	11-21
	S. C.	Spartanburg	3	M	12-18
	Tenn.	Montgomery	11 mo.	M	6-16
	Texas	Bexar	20	M	1-25
	Idaho(NOR)		39	M	4-12
	Utah(NOR)	Sevier	4	M	c.4-30

Doses IPV	Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
4 (2)	III	16	III	3
0	III	22	III	3
5	III	7	III	3
0	III	22	Neg.	3
0	III	15	-	3
2 3	III	7 or 14	II***	3
0	III	10	-	3
4	III	19	Neg.	3
0	III	19	Neg.	4
3	III	16	III	3
0	III	15	Neg.	3
0	III	24	Neg.	4
0	III	17	Neg.	3
0	III	7	III	4
0	III	19	III	4
0	III	11	III	4
0	III	20	Neg.	4
5	III	13	III	2
3	III	16	III	3
5 or 6	III	20	III	3
Unk	III	8	III	2
4	III	19	III	3
0	III	14	Neg.	3
0	III	14	Neg.	3
0	III	25	-	5
0	III	25	Neg.	3
0	III	10	III	3
0	III	10	III	3
0	III	12	III	2
Unk	III	26	III	4
4	III	c.9	III	4

C. Cases Following Type III

	State	County	Age	Sex	Onset	Doses IPV
1964						
	Ala.	Escambia	18	M	1-26	0
	Ala.	Escambia	28	M	3-28	0
	Ill.	Adams	3 mo.	M	1-28	0
	Neb.	Lancaster	41	M	3-14	5
	Ohio	Lucas	8 mo.	M	c.4/3	0

D. Cases Following Trivalent

1964						
	N. Y.	Nassau	37	M	4-27	0
	N. C.	Alamance	43	M	3-16	0
	N. C.	Forsyth	43	M	3-9	0
	N. C.	Mecklenburg	48	M	4-7	0

II. Cases Adjudged "Inconclusive" by Special Advisory Committee

A. Cases Following Type I

1962						
	Calif.	Alameda	11	M	9-27	4
	Calif.(NOR)	Los Angeles	33	M	11-6	0
	La.	Allen	11	M	11-22	4
	Mass.	Hampden	11	M	7-22	4

B. Cases Following Type III

1962						
	N. Y.	Onondaga	49	M	6-18	0
1963						
	Calif.	Kings	10 mo.	M	4-1(?)	0

Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
III	21	III	3
III	20	III	3
III	11	III	2
III	5	-	3
III	c.10	III	3
Tri.	8	II	3
Tri.	15	I	5
Tri.	8	II	4
Tri.	16	III	3
I	4	Neg.	3
I	9	Neg.	-
I	18	I	3
I	30	Neg.	4
III	26	Neg.	3
III	22-29(?)	-	3

B. Cases Following Type III

	State	County	Age	Sex	Onset	Doses IPV
1963	(Cont'd.)					
	Wis.	LaCrosse	38	F	5-4	3
1964						
	N. J.	Mercer	35	M	2-1	0
	N. J.	Morris	41	F	3-23	4

III. Cases Adjudged "Excluded" by Special Advisory Committee

A. Cases Following Type I

1962						
	Calif.	San Benito	8	M	9-27	4
	Calif.	Marin	30	M	10-7	3
	Mass.	Bristol	7	M	6-15	5
	Mont.	Park	39	F	10-16	3
	N. Y.	Nassau	3	M	5-29	2
1963						
	Idaho	Ada	47	M	3-12	0
	La.	Evangeline	10	M	2-14	0
	La.	Rapides	4	M	4-14	5

B. Cases Following Type II

1962						
	Neb.	Douglas	5	F	10-1	4
	Ohio	Mahoning	2	F	2-23	2
	Ohio	Cuyahoga	67	M	7-28	0
	Ohio	Huron	71	M	10-24	0
	Texas	Dallas	7	F	11-21(?) 12-24(?)	4

Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
III	13	Neg.	3
III	13	Neg.	3
III	22	Neg.	2
I	4	I	4
I	14	III	2
I	27	I	2
I	9	-	2
I	23	I	1
I	2	I	4
I	4	I	2
I	7	I	3
II	15	Cox. A-10	1
II	8	III	3
II	6	Neg.	3
II	3	-	3
II	(?)	-	2

C. Cases Following Type III

	State	County	Age	Sex	Onset	Doses IPV	Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
1962										
	Mass.	Norfolk	4	M	7-2	4	III	26	-	2
	Mass.	Suffolk	54	F	7-5	0	III	22	-	3
	Neb.	Buffalo	46	M	8-20	0	III	28	-	3
	Neb.	Lancaster	10	M	8-9	3	III	18	-	3
	Oreg.	Multnomah	39	M	5-21	0	III	23	III	4
	Oreg.	Multnomah	6	M	5-25	0	III	27	III	2
	Pa.	Venango	4	M	6-6	5	III	8	III	1
							I	54	I	
	Wash.	Franklin	6	M	6-12	4	III	5	I	1

* Clinical Status at 60 Days:

1 - Complete recovery
2 - Minor involvement
3 - Significant disability
4 - Severe disability
5 - Fatal

** Specimen taken 2 days after receiving Type II vaccine

*** Specimen taken 8 days after receiving Type II vaccine

C. Cases Following Type III

Terms	Cases	Age	Sex	Onset	Type	Interval (Days) Dose1	Dose2	Fol.	60-Day Status
						DPV	DPV to Onset		
1962 Ohio, Mass.,									
Jan-Mar	Northampton	4	M	12-24	III	0	22	5	-
	Suffolk	54	F	7-5	III	0	22	5	-
Nov.-Dec.	Buffalo	46	M	8-20	III	0	28	5	-
Mich., Tenn., Ore., Wash., Pa., Va., Calif., Mass.,	Lakewood	10	M	8-8	III	2	18	5	-
	Multnomah	39	M	12-21	III	0	22	4	III
	Martinsburg	6	M	2-25	III	0	27	2	III
	Youngstown	40	M	6-6	III	2	8	1	III
							54		
	Franklin	6	M	6-12	III	4	5	1	I

*Clinical Status at 60 Days:

1 - Complete recovery
2 - Minor involvement
3 - Significant disability
4 - Severe disability
5 - Fatal

** Specimen taken 8 days after receiving Type II vaccine
*** Cases following Type II vaccine

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Northern Front.
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